March 26, 2018

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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In re: Bard IVC Filters, Products Liability Litigation	MD-15-02641-PHX-DGC
Sherr-Una Booker, an individual, Plaintiff, v. **C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,** Defendants.	Phoenix, Arizona March 26, 2018 12:58 p.m. CV-16-00474-PHX-DGC

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

JURY TRIAL - DAY 8 P.M.

(Pages 1732 through 1875)

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared by Computer-Aided Transcription

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March 26, 2018

I N D E X

TESTIMONY

WITNESS	Direct	Cross	Redirect	Recross
AUDREY FASCHING, PH.D.	1738	1744		
PAUL BRIANT, PH.D.	1755	1797		
ROBERT M. CARR, JR.	1810			

E X H I B I T S

Number		Ident	Rec'd
5017	Aug. 5, 1999 R&D Technical Report RNF Migration Study, Design Verification (RD-RPT-100)	1829	1830
5022	RD-LNB-087 Laboratory Notebook	1826	1828
5126	Guidance for Industry and FDA Reviewers/Staff - Guidance for Cardiovascular Intravascular Filter 510(k) Submissions	1831	
5164	July 8, 2003 Fax IMPRA to FDA re Recovery Retrievable (K031328)	1852	1853
5178	Oct. 25, 2002 Letter IMPRA to FDA re Recovery (K022236)	1848	1849
5179	Oct. 4, 2002 Letter FDA to IMPRA re Recovery (K022236)	1847	1847
5182	Aug. 30, 2002 Letter IMPRA to FDA re Recovery (K022236)	1845	1846
5187	Aug. 5, 2002 Letter FDA to IMPRA re Recovery (K022236)	1842	1843

E X H I B I T S (Continued)

Number		Ident	Rec'd
5189	July 10, 2002 IMPRA Recovery Permanent Special 510(k) (K022236)	1839	
5232	ETR-05-01-06 (G2® Femoral System Acute Animal Study Report) (followed TPR-04-12-20)	1833	1834
5252	ETR-04-03-02 (RNF v. Competitive Product -- migration resistance)	1835	1836
5296	G2 Filter Product Performance Specification, v.2	1857	1858
5301	ETR-05-01-06 Animal Model Evaluation of Recovery Filter G1A Femoral System Report	1860	1860
5302	TPR 05-01-13 G1A Recovery Filter Femoral System Design Verification and Validation Protocol'	1861	1861
5303	ETR-05-02-05 (G2® DV&V summary testing)	1862	
5304	ETR 05-02-11 G1A Recovery Filter Femoral System Chronic Animal Study Report	1861	1861
5523	ETR-04-03-05 (RNF Characterization testing comparing GFO v. NMT manufactured filters) (followed TPR-04-02-02) ETR-04-03-05, Rev. 0 (GFO and NMT Manufactured Recovery; Filters Migration Resistance Comparison, Phase 1)	1838	1838
5526	TPR-04-02-02 (Protocol for RNF Migration Testing v. Competitive) Test Protocol Number TPR-04-02-02 (Rev. 0) -- Characterization of the Recovery Filter (RF) - Migration Resistance	1834	1835
6082	FDA_PRODUCTION_00001288 -- July 2, 2003 Email chain FDA and BPV re Recovery Retrievable (K031328)	1850	

MISCELLANEOUS NOTATIONS

RECESSES

P R O C E E D I N G S

(Jury enters at 12:58.)

(Court was called to order by the courtroom deputy.)

THE COURT: Thank you. Please be seated. You may continue, Mr. Condo. 12:59:42

MR. CONDO: Thank you, Your Honor.

Ladies and gentlemen of the jury, we were talking before the break about the arm fracture and I want to transition to the leg fracture on the Booker filter.

(AUDREY FASCHING, PH.D., a witness herein, was previously duly sworn or affirmed.) 12:59:57

DIRECT EXAMINATION (Continued)

BY MR. CONDO:

Q. Dr. Fasching, did you photograph the leg filter fracture to document the evidence you observed that allowed you to form an opinion as to the type of the fracture observed? 01:00:11

A. I did.

Q. Okay. And did you prepare a demonstrative exhibit to allow you to explain that to the jury?

A. I did. 01:00:31

MR. CONDO: Would you put up Exhibit 7468, please.

BY MR. CONDO:

Q. Is this your Trial Exhibit or demonstrative exhibit?

A. It is.

MR. CONDO: We would offer Exhibit 7468. 01:00:43

THE COURT: As a demonstrative? 01:00:46

MR. CONDO: As a demonstrative.

MR. O'CONNOR: No objection.

THE COURT: Okay. It's admitted. You may display it. 01:00:54

MR. CONDO: Thank you, Your Honor.

BY MR. CONDO:

Q. Now, can you explain to the ladies and gentlemen what these two photographs depict and what the evidence of fracture is that you identified on this fracture face from the leg? 01:01:05

A. Okay. So this is the fracture surface of the leg on the filter side so that was attached to the filter. Again, it's a pretty classic fatigue fracture surface.

As I had pointed out earlier, you can see the river patterns, which I'm marking on here essentially, and they point back to where the fracture initiation site was that I indicated with a red arrow. 01:01:32

On this same fracture, the fatigue crack propagates along until the cross-section is no longer able to maintain the stresses and then it will fail quickly by overload. And that section, I'll draw a line on the demarcation, this is a fatigue fracture and then the back half there, that small part is the overload zone. 01:02:05

Q. Thank you.

Now, I want to talk about the other 29 filters 01:02:25

excluding Ms. Booker's filter for purposes of our discussion. 01:02:29
So let's talk about the other 29 filters that you examined as part of your analysis. Have you formed an opinion to a reasonable degree of engineering and scientific certainty as to the types of fractures that you observed in those other 29 01:02:44
filters?
A. Yes.
Q. And what is that opinion?
A. They were bending fatigue fractures with the exception of I think two fractures. 01:02:56
Q. And what were the two fractures that were not bending fatigue fractures?
A. Those two fractures were located in the foot or hook portion of legs. They were all overload so it looked like when you would get overload like that, they probably happened during 01:03:15
the retrieve process.
Q. And did Ms. Booker's filter have any overload fractures in the feet or hooks?
A. No.
Q. Now, did you also form an opinion to a reasonable degree 01:03:28
of engineering and scientific certainty as to the likely causes of the fractures in those 29 other filters?
MR. O'CONNOR: Objection. Lack of disclosure.
THE COURT: All right. Where is that, Mr. Condo?
MR. CONDO: Your Honor, it is in the April 14, 2017 01:03:49

report, Section 5.2 , page 16, the very top in bold. 01:03:54

MR. O'CONNOR: Okay. Withdraw the objection.

THE COURT: All right.

BY MR. CONDO:

Q. You can answer. 01:04:16

A. Can you repeat it?

Q. Sure. Did you form an opinion to a reasonable degree of engineering and scientific certainty as to the sources or causes of the fractures in the 29 filters other than Ms. Booker's filter? 01:04:30

A. I did.

Q. And what is your opinion?

A. My opinion was that there was no one source of loading or feature or -- yeah, feature or design or manufacturing on any of the filters that led to the fractures. 01:04:47

Q. Okay. And have you formed an opinion to a reasonable degree of engineering and scientific certainty as to whether there was any correlation exhibited among the fractures that you examined in the 29 filters?

MR. O'CONNOR: Objection. Not disclosed, Your Honor. 01:05:04

THE COURT: All right.

Mr. Condo?

MR. CONDO: 5.2, page 16, the bottom of the very first paragraph under Section 5.2.

THE COURT: Objection overruled. 01:05:33

MR. O'CONNOR: I withdraw, Your Honor. 01:05:34

THE WITNESS: So there was really no correlation between when I was evaluating the fractures when we were looking at -- I looked at location and direction of bending of the fractures in that type of aspect. They were all unique. 01:05:53

BY MR. CONDO:

Q. And what does the absence of a correlation tell you about those 29 filter failures?

A. That would tell me that each filter was experiencing its own set of forces on it that ultimately led to this type of fracture. 01:06:12

Q. Now, your sample of 29 retrieve filters, included Recovery, G2, and G2X filters; correct?

A. Correct.

Q. Did you make any comparison between the arm and leg fractures in the Recovery filter versus the arm and leg fractures in the G2, G2X, retrieved filters? 01:06:32

A. Yes.

Q. And what were your findings?

A. Well, so in the Recovery filters, I looked at 13 Recovery filters and I don't remember -- 36, I'm sorry, 36 arm fractures in the Recovery filters. In the G2 and G2X filters, I looked at 16 filters and there were 15 arm fractures. 01:06:48

Q. And what did you conclude from those fractures?

A. There were several design changes made to the arms between 01:07:34

the Recovery filter and the G2 filter which included the -- sorry, length of the arm and the tipping of the ends and there were fewer fractures per filter between Recovery and G2. So to me it appeared like the design changes made a difference in the number of fractures I was seeing in the filters. 01:07:36 01:08:05

Q. The G2X and G2 design changes improved the fracture resistance of the filter?

A. Yes.

Q. Now, do you agree that tilt migration and perforation have the potential to change the loading experienced by the filter in the vena cava? 01:08:24

A. Yes, I do.

Q. And did you do a literature search as part of your analysis to determine whether or not there are peer-reviewed studies that have been published to establish a correlation between perforation and fracture of the IVC filter? 01:08:36

A. Yes.

Q. Did you find any peer-reviewed studies that established a correlation?

A. I did not. 01:08:48

Q. From what you observed, did you see any evidence that Booker's filter fractures were caused by design defect?

A. I did not.

Q. No evidence of a design defect that you observed?

A. No. 01:09:02

Q. That's a correct statement? 01:09:02

A. Yes.

MR. O'CONNOR: Objection, nondisclosure on that, Your Honor.

THE COURT: Where is that? 01:09:06

MR. CONDO: It's in the deposition, Your Honor.

MR. O'CONNOR: No. It's not --

THE COURT: It can be in a deposition as well. That's what my Reporter says. Where is it in the deposition?

MR. CONDO: May I approach, Your Honor? 01:09:19

THE COURT: Yes. Come on up.

(At sidebar 1:09.)

THE COURT: Okay. Thank you. I don't know if she heard that. You need to say that so it's on the record.

MR. O'CONNOR: I'm withdrawing the objection. 01:09:48

THE COURT: Thanks.

(End of sidebar discussion.)

MR. CONDO: Thank you, Dr. Fasching. I have no further questions.

THE COURT: Okay. 01:10:00

CROSS - EXAMINATION

BY MR. O'CONNOR:

Q. Good afternoon, Dr. Fasching. We've met before, haven't we?

A. Yes, we have. 01:10:38

Q. And again, I'm Mark O'Connor. I met you up in California and took your deposition at one time. Do you recall that? 01:10:39

A. I do recall.

Q. Now, I want to talk to you, first of all, about these 29 filters setting aside Sheri Booker's. Those all came to you at different points in time; fair? 01:10:51

A. Yes, that's true.

Q. And each filter came to you with a specific request from Bard to analyze that individual filter for whatever purpose Bard was looking at; true? 01:11:08

A. The filters came to me and I was asked to do the same thing every time. I followed the same protocol to analyze the number of fractures and look at what the mode of fracture was, location.

Q. I understand. So each filter came to you from Bard at different points in time; true? 01:11:27

A. Yes.

Q. And you individually looked at each filter; correct?

A. Yes.

Q. Bard has not sent you every fractured Recovery or G2 that it is aware of, has Bard? 01:11:38

A. I don't know. I don't think they have. I don't know.

Q. You know that there have been more fractures and more perforations out there that you have ever seen; true?

A. That's true. 01:11:56

Q. And what you have seen are cases of 29 filters where 29 patients had failures, had to have surgeries to have those filters removed; right? 01:11:57

A. Yes.

Q. And after they are removed, Bard sent those to you to look at, fair? 01:12:10

A. Well, I don't think -- Bard didn't send them to me. They were sent to me but Bard requested they were sent to me.

Q. I apologize. They were sent to you by Bard's lawyers?

A. No. They were usually sent to me by a third-party lawyer or a cleaning facility or -- 01:12:29

Q. Isn't it fair to say that Bard's lawyers are the people that requested you to do the examinations?

A. Yes.

Q. And so it wasn't Bard, the company, was it? 01:12:41

A. No.

Q. It was the lawyers?

A. Yes.

Q. And you don't receive medical records with those filters when you receive them, do you? 01:12:56

A. No, I don't.

Q. And you can't tell this jury, when you talk about each of the 29 filters, what position those filters were in when the surgery was done on any of those 29 patients to remove the filter, can you? 01:13:10

A. That's true, I cannot. 01:13:11

Q. And whether the filters were tilted or what position they were in when perforating, you simply don't know?

A. I don't know.

Q. And depending on how a filter was tilted, how it perforated through a vena cava would affect the loads that were placed on that filter; true? 01:13:24

A. It could possibly affect the loads.

Q. But you have not studied loads or stresses in people, have you? 01:13:38

A. No.

Q. Is that correct?

A. That's correct.

Q. And so that's completely outside of your area. You can't tell the jury what types of loads, what type of stresses, what types of forces happen to a filter in any position after it's implanted in a patient. Fair? 01:13:46

A. Well, I know that they were bending forces. That's very clear from the fracture surface.

Q. Understood, because that's what you saw. Every filter you saw broke because of fatigue; right? 01:14:03

A. Bending fatigue.

Q. But just so you and I are on the same page, you have never analyzed the stresses or strains imposed on a filter after it's implanted in a human being, have you? 01:14:17

A. I have not.
Q. You have not received any documents from Bard regarding statistically significant comparative analyses of the complications between its filters, have you?
A. No. 01:14:39
Q. And Bard has never sent you any type of root cause analysis -- or its lawyers, excuse me, haven't sent you any type of root cause analysis that was done by Bard to investigate failure modes; true?
A. I have not seen those. 01:14:57
Q. And you told us that you made $300,000 over the years working on these cases, your company has; right?
A. I was going to say, yeah. I haven't but my company has.
Q. Your company makes that money because you're doing the work? 01:15:11
A. Yes.
Q. But in the time that you have been doing these examinations, Bard has never or its lawyers have never asked you to perform a root cause analysis to determine why its filters are fracturing; fair? 01:15:25
A. I have not, no.
Q. And Bard has not asked you or your company to do a root cause analysis on the Recovery or G2 to find out why the filters migrate, tilt, or to find out why they perforate; is that true? 01:15:48

A. That is true.
Q. In essence, Bard has never come to you or Bard's lawyers have never come to you and said, "Dr. Fasching, would you please analyze for us why filters, the G2 and the Recovery, are fracturing?" Fair? 01:16:19
A. I analyzed -- well, I analyzed why they fracture. They fracture due to bending fatigue.
Q. But they have never asked you to do a root cause to assess the issue of fracture for any filter; true?
A. I haven't done a root cause on any filter. 01:16:37
Q. Now, you mentioned something earlier about microscopic examinations. You know that one was done on our side; true?
A. Yes.
Q. And you know that Dr. McMeeking is a different type of engineer than you; correct? 01:17:00
A. Yes.
Q. And what Dr. McMeeking does is he does things like finite element analyses; correct?
A. Yes.
Q. You don't, do you? 01:17:10
A. No.
Q. You've never even designed a Finite Element Analysis, have you?
A. No, I'm not a mechanical engineer.
Q. And you're certainly not an expert in finite element 01:17:20

analysis, are you? 01:17:23
A. I am not.
Q. And you have not done any work or studies to determine what types of stresses and strains are imposed on a Bard IVC filter after it's implanted, have you? 01:17:37
A. No.
Q. Correct?
A. That is correct.
Q. You haven't even analyzed Bard's own testing to address stresses and strains imposed on a filter after it's implanted, 01:17:50
have you?
A. No.
Q. So in terms of whether -- how that testing works or whether it's effective, you simply can't tell the jury today, fair? 01:18:03
A. That's right.
Q. You haven't designed an IVC filter?
A. No.
Q. In fact, you haven't performed any tests on IVC filters, have you? 01:18:14
A. No.
Q. Correct?
A. Correct.
Q. And you yourself have not studied the anatomy and physiology that affects Bard filters after they are implanted, 01:18:23

have you?
A. No.
Q. You agree that a medical device company like Bard must understand the worst case scenarios and all potential high-stress loading conditions before it releases the filter in the market? You agree with that, don't you? 01:18:28 01:18:42
A. I think that medical device companies need to understand the loading conditions to the best of their abilities.
Q. Well, the words you used in your deposition to me was high-stress loading conditions. Do you remember that? 01:18:55
A. I don't remember specifically but whatever the high-stress loading conditions are.
Q. Simply something you don't know once the filters are implanted; true?
A. What the high-stress loading conditions are? I don't know what they are. 01:19:09
Q. Thank you.
All the fractures that you have seen in the individual 29 that Bard sent you one by one over the years have been fatigue fractures; correct? 01:19:22
A. Not all of them have been fatigue fractures.
Q. With the exception of the two, I thought you said the others have been.
A. Yes.
Q. Bard or its lawyers have never provided you with internal 01:19:34

tracking and trending data regarding whether the filters were fracturing at higher rates than their own engineers predicted. True? 01:19:38

A. I don't have that data.

Q. And in fact, Dr. Fasching, you do not know what patterns of fracture exist in Bard's internal tracking and trending of the G2 filter; correct? 01:20:00

A. I don't know.

Q. True?

A. That is true. 01:20:11

Q. And you haven't asked Bard's lawyers to provide you with any tracking or trending information correct?

A. I have not asked. I think it's -- yeah. I would need to look at the samples myself to do it the same way that I had been doing it. 01:20:30

Q. Isn't it true, Dr. Fasching, that if Bard recognized that the G2 was failing at rates higher than predicted by its engineers, that could impact your opinion whether filter fractures were caused by a design defect; correct?

A. When I -- what I use to arrive at my opinion on whether the filter's fractured due to a design defect was based on the -- my analysis of location, direction of bending, and the information that I gathered from looking at the individual filters. 01:20:48

Q. My question is different. I'm just going to something you 01:21:14

told me in your deposition back in June of 2017. If Bard, the medical device company that made the Recovery and G2, recognized that the G2 was failing at rates higher than predicted by its engineers, that could impact your opinions on whether filter fractures were caused by a design defect. Do you agree that you gave me that testimony? 01:21:17 01:21:36

A. I don't remember making that statement. I don't know how rates would affect my opinion.

Q. I'm going to go to your June 26, '17, deposition.

MR. O'CONNOR: And, Greg, if you could get to page 27, please. 01:21:50

You know what, I can't find that question so I'll withdraw that question, Your Honor.

BY MR. O'CONNOR:

Q. Dr. Fasching, in any of the 29 cases, you have never developed or designed a test to correlate your results with the finite element analysis; fair? 01:23:28

A. I have not.

Q. And you do not know if Bard suggested any types of testing protocol to determine how to eliminate or lower stresses imposed on a filter; fair? 01:23:48

A. I'm not aware of what Bard's testing protocol was.

Q. Now, you do know that Dr. McMeeking reviewed comparative analyses done by Bard? You're aware of that?

A. Yes. 01:24:10

Q. And you have not? 01:24:11
A. I have not.
Q. And finally, Dr. Fasching, if you, as an engineer, assumed that Bard or knew that Bard was aware of failures in its filters, you would expect Bard to take immediate steps to 01:24:40
protect patient safety if it was aware of its failures and it is filters; correct?
MR. CONDO: Outside the scope.
THE COURT: Sustained.
MR. O'CONNOR: All right. That's all I have. Thank 01:25:09
you.
THE COURT: Redirect?
MR. CONDO: No further questions.
THE COURT: Okay. Thank you, ma'am. You can step down. 01:25:15
THE WITNESS: Thank you.
(Witness excused.)
MR. NORTH: Your Honor, at this time we would call Dr. Paul Briant to the stand.
COURTROOM DEPUTY: Sir, if you'll please come forward 01:25:53
and raise your right hand.
(PAUL BRIANT, PH.D., a witness herein, was duly sworn or affirmed.)
COURTROOM DEPUTY: Could you spell your the last name for us, please. 01:26:06

THE WITNESS: B-R-I-A-N-T. 01:26:07

COURTROOM DEPUTY: Thank you, sir. Please come up and have a seat.

DIRECT EXAMINATION

BY MR. NORTH: 01:26:27

Q. Good afternoon, Dr. Briant. Could you tell the members of the jury what your profession is?

A. Sure. I'm a mechanical engineer.

Q. And what is a mechanical engineer?

A. Mechanical engineer is someone who designs and analyzes mechanical structures. 01:26:36

Q. And by whom are you employed?

A. I work at a company called Exponent Failure Analysis Associates.

Q. And where are your offices located? 01:26:55

A. Our headquarters is in Menlo Park, California.

Q. Is that outside the San Francisco?

A. Yes.

Q. Could you tell the members of the jury your educational background? 01:27:06

A. Sure. So I did my undergrad at Washington University in St. Louis where I got my bachelor of science in mechanical engineering, graduated summa cum laude from there. I then went on to Stanford University where I got my master's degree again in mechanical engineering and my Ph.D. also in mechanical 01:27:23

engineering. 01:27:26
Q. And what was the topic of your Ph.D. research?
A. For my Ph.D. research I look at tissue mechanics so I was focused on cartilage in the knee and understanding how the stresses and strains apply to knee articular cartilage 01:27:38
interact. The motivation for this was understanding knee osteoarthritis.
Q. Are you a licensed engineer?
A. Yes. I'm a professional engineer.
Q. Could you tell us what sort of work Exponent Failure 01:27:51
Analysis Associates engages in?
A. Sure. We're a technical consulting firm. We focus largely on failure analysis and trying to understand why structures are failing.
Q. How long have you been employed with Exponent? 01:28:09
A. I have been there for ten years.
Q. And what is your position there?
A. I'm a principal engineer.
Q. And why do companies generally come to Exponent to perform an analysis? 01:28:21
A. Sure. They come for a couple of reasons. I'll speak mostly for medical device work here. They come either to analyze their devices, test their devices, understand them, either because they don't have the expertise in house or more, importantly, we're often an independent reviewer of their 01:28:36

device.
Q. Are you familiar with a substance called Nitinol?
A. Yes.
Q. And have you had any involvement with Nitinol from a professional standpoint? 01:28:50
A. Yes. I do a lot of work in cardiovascular medical device and a lot of them are made of Nitinol.
Q. Have you -- what sort of work specifically did you do with Nitinol?
A. So I do a lot of work on analyzing the stresses and 01:29:00
strains in cardiovascular devices that are made of Nitinol. And I've presented on it at engineering conferences and published papers on it, things like that.
Q. Can you estimate how many papers you've published on Nitinol related topics? 01:29:18
A. In terms of journal articles, one or to. In terms of conference presentations, three, four, five, something like that.
Q. You mentioned cardiovascular Nitinol products. What sort of devices were those? 01:29:33
A. It ranges all over the map from stents, which are put into blood vessels, heart valves, IVC filters, things like that.
Q. Are you familiar with a Dr. McMeeking who has testified in this case?
A. Prior to this litigation, I didn't know him but I'm, 01:29:48

obviously, familiar with him now. 01:29:51

Q. Now, you were retained by my law firm in this particular litigation?

A. Yes.

Q. And what were you asked to do? 01:29:59

A. I was asked to review the opinions that Dr. McMeeking made and the calculations that he did as a basis for those opinions.

Q. Who determined what your methodology would be in undertaking this analysis?

A. I did. 01:30:15

Q. What percentage of your professional time is currently spent on litigation-related matters?

A. It's about 40 percent of my time. The other 60 percent of my time is working directly with companies, analyzing their devices in various ways. 01:30:32

Q. And what industries do you generally provide failure analyses to?

A. So it's a range of industries for myself personally. But the two that I focused on mostly are medical devices and then consumer electronics and other technical electronics products. 01:30:45

Q. What documents were you provided to review in this matter?

A. I was provided reports by Dr. McMeeking and other experts and the supporting references that were in those reports.

Q. Were you provided various materials regarding the development of the G2 and Recovery filters? 01:31:15

A. Yes. 01:31:17
Q. What sorts of materials?
A. I was provided the design history files, the 510(k) submission documents, things like that.
Q. Were you provided testing materials? 01:31:28
A. Within those documents was a summary of testing that was performed.
Q. And how were the documents you received selected?
A. They were generally the references that were in the other expert reports and if I wanted anything in particular, I 01:31:41 requested it.
Q. And did you read reports of other experts who have testified in this matter?
A. Yes.
Q. Do you know Dr. Fasching? 01:31:55
A. Yes.
Q. Did you rely on any of the reports or depositions taken in this case to form your opinions?
A. So, obviously, Dr. McMeeking's opinion -- or report. Other than that, not really. 01:32:12
Q. Did you review every document referenced in Dr. McMeeking's reports?
A. I don't know if I reviewed all of them but certainly most of them.
Q. Now, as a part of your work to analyze the stress and 01:32:27

strains on these filters, did you conduct a number of tests at your facility? 01:32:32

A. Yes. We performed both analyses and testing at Exponent.

Q. And did that involve sophisticated equipment?

A. Sure. Both the calculations that we performed, we used a technique calls finite element analysis which is a numerical analysis technique as well as the laboratory bench testing that we did. 01:32:46

Q. And did -- did other people that work with assist you in conducting these tests and experiments? 01:33:00

A. Yes. A handful of people, engineers at Exponent as well as technical staff.

Q. And have you charged for the testing and efforts you've done performed in this case?

A. Yes. 01:33:18

Q. And can you tell us approximately how much Exponent has charged for all of its testing?

A. Over the five or so years that we have been involved, I believe the total is about $600,000.

Q. Now, are you an employee or owner of Exponent? 01:33:34

A. I'm an employee.

Q. Are all of the billings that Exponent has provided for the work on this case over five years, does that reflect only your time?

A. No. That reflects both myself as well as the team. 01:33:46

Q. Are you a salaried employee of Exponent? 01:33:54
A. Yes, I am.
Q. Is your compensation in any way contingent on the number of hours you bill?
A. Not really, no. I get a salary, whatever it is. 01:34:03
Q. Do the billings of Exponent include some costs associated with the equipment used to perform these tests?
A. Yes. We charge for that as well.
Q. Now, as a result of the work and investigation that you have done in this case, have you reached any opinions? 01:34:23
A. Yes, I've reached some opinions.
Q. Could you tell us what those opinions are briefly?
A. Sure. To summarize them, so as you probably heard previously, Dr. McMeeking, who is the mechanical engineering expert put forth by the plaintiffs, came up with a series of 01:34:39 claims regarding the Bard filters and performed some analyses upon which he bases some of those claims and also had some criticisms of the testing analysis that Bard performed during their design phase.
And so my opinions boil down to three main things. 01:34:56 Number one is that the analyses that Dr. McMeeking performed are unreliable in that this is due to the assumptions and simplifications that Dr. McMeeking used. He simplified things in the way he calculated them way down and had to make several assumptions that were beyond physical limits of what the human 01:35:17

body can do in order to do those calculations. 01:35:20

Q. And what other opinions did you reach?

A. Sure. Second opinion is that the criticisms that Dr. McMeeking made regarding the Bard testing and analyses that they did, the testing and analysis that Bard did considered all 01:35:35 the relevant complications that are put forth in industry standards and guidance documents from regulatory bodies. And in addition, Dr. McMeeking, while criticizing the Bard work, didn't put forth any opinions of his own or any ideas of his own about how Bard may have modified those tests. 01:35:56

Lastly, is the Simon Nitinol filter, which I'm sure you've heard about from an opinion from an engineering perspective, the Simon Nitinol filter is not an alternative design for the Bard retrievable filters because it lacks the functionality and benefit of being retrievable. 01:36:14

Q. Did you prepare a summary of those opinions that you just recited for us?

A. Yes. I prepared a slide that summarizes that.

MR. NORTH: Could you bring up 7809?

BY MR. NORTH: 01:36:40

Q. And, again, was this prepared by you to help illustrate your opinions to the jury?

A. Exactly.

MR. NORTH: Your Honor, at this time we would tender 7809. 01:36:49

THE COURT: Any objection to this being used as a demonstrative? 01:36:51

MR. O'CONNOR: No objection.

THE COURT: All right. You may use it for that purpose. 01:36:57

MR. NORTH: Thank you, Your Honor. Could we display this?

BY MR. NORTH:

Q. Did you prepare these pictures or diagrams here to the right? 01:37:20

A. Yes, I did.

Q. And what are those supposed to depict as far as your opinions go?

A. Sure. Those relate largely to opinion number one and illustrate the general methodology that Dr. McMeeking used and 01:37:31 the simplifications that were made relative to the analysis that I performed on the Bard IVC filters. As we'll discuss later, the calculations I performed in terms of analyzing the filter incorporated the whole filter which is shown in the middle there on the image, the IVC, the surrounding tissues, 01:37:52 and everything like that.

Q. Let me ask you this, Dr. Briant. As part of your work, have you examined an actual Bard filter?

A. Yes, I have.

Q. And what did you do with those Bard filters that you 01:38:06

examined? 01:38:09
A. So the Bard filters that we received, I received several Recovery filters, G2 filters and Denali filters; and with those filters we performed mechanical bench testing to validate the models of the calculations that we had done. 01:38:23
Q. Have you reviewed any material specific to Ms. Booker?
A. I've reviewed expert reports specific to her.
Q. Have you reviewed any of her medical records?
A. No, I haven't.
Q. Are you aware of the types of events that Ms. Booker experience with her G2 Filter? 01:38:38
A. Yes, I am.
Q. And what are those?
A. The filter suffered a fracture of one of the arms and one of the legs fractured in two locations and also there was tilt and perforation. 01:38:49
Q. Now, can you further explain -- let's look at your first opinion. Can you further explain to us why it is that you believe Dr. McMeeking incorporated incorrect assumptions?
A. Sure. Absolutely. So the -- as you can see in the picture on the right, Dr. McMeeking performed a series of analytical calculations that incorporated just the upper portion of the filter, which is shown in blue, and the rest of it is omitted as you can see there. 01:39:06
He also made several assumptions that were needed in 01:39:24

order to form his calculations analytically. He assumed that the IVC was essentially infinitely stiff, essentially rigid, which we know isn't true. It's about as stiff as a rubber band. 01:39:26

He also assumed that the motion of the IVC, because he assumed it was infinitely stiff, didn't change due to the presence of the filter so the motion remained the same. And also that the rotation of the filter when it contacted the IVC, which is shown by that red X there, that rotation was constrained. 01:39:42 01:40:04

Q. Did you -- did Dr. McMeeking in this case analyze filter arm strain and stress?

A. Yes, he did.

Q. And how did he do that? Through what vehicle?

A. Through the analytical calculations that I was just describing. 01:40:16

Q. Did he conduct any bench testing?

A. No, he did not do any bench testing.

Q. Did you prepare a demonstrative exhibit to help you explain what stress and strain is as part of the analysis you conducted here? 01:40:31

A. Yes, I did.

MR. NORTH: If we could show 7811.

Your Honor, we would tender 7811.

MR. O'CONNOR: No objection to the demonstrative. 01:40:58

THE COURT: All right. You may display it. 01:40:59

BY MR. NORTH:

Q. If you would use this demonstrative exhibit, Doctor, to explain for the jury in your particular line of analysis what stress, strain, and stiffness mean? 01:41:14

A. Sure. Absolutely. So these are tree terms we'll be talking about a bunch today. So stress is the amount of force that you apply to an object. So it's a measure of how much load you put on it.

In the image there on the right, the stress would be 01:41:30 essentially the weight that you apply. We show a rod hanging and then hanging a weight on it and it stretches out. So the stress would be the amount of force.

Strain is how much the object deforms. So if you have a rubber band and you pull it, it's a measurement of how 01:41:45 much it's stretched under a certain force.

And lastly is stiffness. So stiffness is the ratio of those two things, meaning that steel, which is a very stiff structure, if you put a force on it, won't deform nearly as much as if you have a rubber band which is very soft. So 01:42:01 stiffness is a measure of how much strain you get for a given amount of stress.

Q. And what in particular was Dr. McMeeking evaluating about arm strain with a filter?

A. So Dr. McMeeking was calculating the strains in the arm 01:42:14

filter near the cap or where the arms enter the cap. And he analyzed the strains and essentially a pair of filter arms, not the entire filter. 01:42:19

Q. And did Dr. McMeeking make an assumption by using only the upper arm of a filter to conduct his analysis? 01:42:37

A. He made several assumptions that I outlined previously in terms of the motion of the IVC and, obviously, simplified the analysis by only incorporating the upper portion of the arm.

Q. And do you have any criticisms of his focus on only upper arm in doing these calculations? 01:42:59

A. Sure. As well as with the assumptions. As you'll see when we go through the results of my calculation, when we include the entire filter, include the IVC and the surrounding tissue structures, you get very different results when you don't have to make those assumptions that Dr. McMeeking made. 01:43:15

Q. Did you do anything else in your work other than review and analyze Dr. McMeeking's calculations of arm strength?

A. I did my own calculations and we did bench testing as we've talked about.

Q. Did Dr. McMeeking conducting any bench testing? 01:43:37

A. No, he did not.

Q. Let's talk about the assumptions or inputs that you used in doing your testing.

MR. NORTH: Could we bring up 7812.

\\\

BY MR. NORTH: 01:43:59

Q. 7812, is this an exhibit that you prepared to help demonstrate the assumptions you used in doing your calculations?

A. That's correct. 01:44:07

MR. NORTH: Your Honor, at this time we would tender 7812 as a demonstrative.

MR. O'CONNOR: No objection.

THE COURT: All right. You may use it.

MR. NORTH: Could we display it, Your Honor? 01:44:20

THE COURT: Yes.

BY MR. NORTH:

Q. What impact on the testing do you believe your analysis did use of the complete filter as opposed to a single strut have? 01:44:37

A. Well, so this allowed us to analyze the strains in the IVC from a variety of different loading conditions. As you'll see, we analyzed the stresses and the strains from several different ways in order to try and bound the problem and understand what the strains in the arms could be. 01:44:57

Q. And did you make a different assumption about the surrounding tissue than Dr. McMeeking did?

A. Yes. So Dr. McMeeking, as I mentioned, in order to simplify the calculations in a way that he did, had to assume a certain amount of motion for the IVC and he essentially assumed 01:45:13

that the motion of the IVC remains unchanged when you insert a filter. 01:45:16

So the IVC naturally is just pulsing back and forth due to respiratory loads that are put on it. When you put that filter in an IVC, though, this will add something to the system and will stiffen the system and affect the response of the IVC. However, Dr. McMeeking just assumed that the motion of the IVC didn't change and also assumed that the rotation of the arm as it exits -- as it contacts the IVC, that there was no rotation there. 01:45:29 01:45:50

And both of these will increase the strains. And as you'll see, when I inspected the surrounding issues and used conservative assumptions for those calculations, that you get very different results.

Q. Did you prepare a demonstrative exhibit yourself to help demonstrate the impact of the assumption you made regarding the surrounding tissue of the IVC? 01:46:02

A. Yes, I did.

MR. NORTH: If we could display 7813, please.

BY MR. NORTH: 01:46:28

Q. Is this the demonstrative I just referenced?

A. Yes.

MR. NORTH: Your Honor, at this time we would tender as a demonstrative 7813.

MR. O'CONNOR: No objection. 01:46:37

THE COURT: Admitted. Well, I'm sorry, not admit. You may use it as a demonstrative.

MR. NORTH: May we display, Your Honor?

THE COURT: You may.

BY MR. NORTH: 01:46:52

Q. Dr. Briant, explain for us what this cross-section of the anatomy shows with regard to your assumptions on the tissue of the IVC.

A. Sure. So what this cross-section is, this is a CT scan. This particular one was taken from a medical journal. And the 01:47:06 IVC is highlighted in that full solid yellow circle that's in the middle there. And on the right side of the slide you can see the analysis setup that I used where, again, the IVC is shown in blue and then we have surrounding soft tissue that is shown in green. 01:47:28

And the corresponding locations for the model are shown by the dashed yellow and the dotted yellow line in the CT scan.

As you can see, the IVC is surrounded largely by soft digestive tissues that are quite soft. Nearby, though, you 01:47:45 have the vertebrae which we incorporate into our analysis, that's the orange region in the code plot on the right.

And so this just shows the model setup that we used when performing our calculations and how it's representative of the actual human body. 01:48:06

Q. And how did your assumption again regarding that soft surrounding tissue differ from what Dr. McMeeking assumed in his calculations? 01:48:08

A. So, again, Dr. McMeeking assumed that the IVC was essentially infinitely stiff, that it could withstand any motion, that that was -- or any force that was imparted by the filter as opposed to surrounding it with soft tissues. And at least on me, this region is soft. 01:48:19

Q. And as a part of your work in studying mechanical engineering issues with regard to tissue that you talked about earlier, are you familiar with medical literature that substantiates or supports your assumption about surrounding soft tissue on the other hand, the IVC? 01:48:41

A. Yes. In two ways. So there's been studies that are published in the literature that measure the stiffness as we talked about of the IVC, so they actually have tissue and they pull on it and measure the stiffness and also they measure the stiffness of the surrounding properties. And we incorporated those into the analysis. 01:49:01

Secondly, there's been studies that have been done with IVC filters and they have shown that at the location of the filter, that the IVC moves less than -- away from the filter. So both of those are supportive. 01:49:17

Q. What is a hyperelastic stress-strain response?

A. Sure. So this refers to the way that the stiffness of the 01:49:38

IVC changes as a function of strain. I prepared a demonstrative that shows this. 01:49:45

MR. NORTH: Could we bring up 7685?

BY MR. NORTH:

Q. Is this the demonstrative that you prepared that shows hyperelastic stress-strain? 01:50:04

A. Yes, it is.

MR. NORTH: Your Honor, could we tender 7865 at this time?

MR. O'CONNOR: No objection. 01:50:14

THE COURT: You may use it.

MR. NORTH: Could we display?

THE COURT: Yes.

BY MR. NORTH:

Q. I'm afraid to ask but could you explain to us what this is depicting? 01:50:27

A. Yes. This is getting very mathy. So what we're looking at here is the stress-strain response for the IVC. What we have on the Y axis, or the vertical axis, is stress which is force. On the X axis we have strain which is, again, is how much is responding. 01:50:44

And what you can see is initially you have a soft region. That's shown by the low slope of the line initially and after a while it gets stiffer. This is due to the -- what's called the collagen fibers in the IVC eventually 01:50:58

becoming aligned as you stretch it more and more. And eventually when you start pulling on them in a straight manner, it becomes very stiff, which is why you have this initially soft and then eventually stiff response. 01:51:03

Q. And how did that make -- your consideration of that response make your assumptions different from those of Dr. McMeeking? 01:51:13

A. Well, so this was explicitly incorporated into our calculations as opposed to Dr. McMeeking who assumed that the IVC was infinitely stiff. 01:51:29

Q. Now, were there certain attributes about the substance Nitinol that you considered in assumptions that differed from the assumptions made by Dr. McMeeking?

A. Yes. Nitinol has special properties and you may have heard about these already. It's what's called a superelastic material where it can stretch a lot under relatively little load. I, again, prepared a demonstrative if it's possible to show that. 01:51:48

MR. NORTH: Let's pull up 7677 if we could.

BY MR. NORTH: 01:52:12

Q. Is this the demonstrative that you prepared to explain the differences of Nitinol?

A. Yes, it is.

MR. NORTH: Your Honor, at this time we would tender 7677. 01:52:19

MR. O'CONNOR: No objection. 01:52:20

THE COURT: You may display it.

BY MR. NORTH:

Q. Now, what is Nitinol constitutive relationship?

A. Nitinol constitutive relationship, very similar to what we were looking at on the last slide. This is the stress-strain response for Nitinol and so what happens is kind of almost the opposite of what you have in the IVC. You have an initially stiff region where the slope of the stress-strain curve is high and then you get to what's called a phase transition where you get the slope basically goes to horizontal and you can see the horizontal line in the middle of this curve. You start off in the bottom corner of 00 and work your way up, so it becomes very stretchy after a certain point. And then eventually you get through this phase transition and it stiffens. 01:52:37 01:52:58 01:53:15

Now, this was incorporated into the analysis that I did and this is very common and standard. You had asked about Dr. McMeeking. Dr. McMeeking assumed what's called a linear elastic stress-strain response where he basically just had that first portion and didn't include the superelastic stretchy part. 01:53:32

Q. Is it well-known in the mechanical engineering and materials sciences that Nitinol does have these superelastic properties?

A. Yes. 01:53:47

Q. Do you believe it is possible to accurately model the stresses and strains on Nitinol without taking that superelastic nature of the substance into consideration? 01:53:51

A. It certainly is important to incorporate this.

Q. Did you prepare a demonstrative that summarizes the various different assumptions that you made in your finite element analysis and calculations compared to what Dr. McMeeking did? 01:54:10

A. Yes, I did.

MR. NORTH: Could we display Exhibit 7814? 01:54:22

Q. Is this the demonstrative that summarizes your different assumptions than those used by Dr. McMeeking?

A. Yes it is.

MR. NORTH: We would like to tender 7814, Your Honor.

MR. O'CONNOR: No objection. 01:54:53

THE COURT: You may display it.

BY MR. NORTH:

Q. We just talked about the first one I believe, Dr. Briant, and what, again, is the second one, filter geometry?

A. Sure. So this summarizes, as you said, the differences in the calculations for stress and strain between myself and Dr. McMeeking. 01:55:02

In the first column in blue, there we have various inputs to the model so we have the Nitinol that we talked about, filter geometry, tissue geometry, and the material 01:55:20

properties. And then on the green and the red have the -- what was used in each of the calculations for determining stress and strain. So as you just mentioned for the Nitinol, I utilized the superelastic stress-strain response based on testing from Bard data whereas Dr. McMeeking just had a linear elastic response. 01:55:25 01:55:40

For the filter geometry, as you saw, the analysis included the complete filter as opposed to just the single arm or leg that Dr. McMeeking utilized.

Q. What about tissue geometry, what was the difference there again? 01:55:57

A. Sure. So in the calculations that you saw in the model setup, my calculations included the IVC and the surrounding soft tissues as well as the vertebrae.

Q. And what about the filter motion, were there differences in the assumptions there? 01:56:13

A. Correct. So Dr. McMeeking, as we talked about, assumed that the motion was unchanged by the presence of the filter and IVC just kept on pulsing just the way it had been before. When you incorporate the complete filter and include the IVC and the surrounding soft tissues, you don't have to make that assumption. You can actually calculate what the response would be and that's what my calculations did. 01:56:29

Q. How is it that we know that the IVC will have motion in that circumstance? 01:56:46

A. So we know from literature that the IVC pulses without the filter being present. And it's going to continue to pulse at some level and it's a question of how much does it continue to pulse when you insert a filter into that situation. 01:56:48

Q. And does the filter impact that movement or pulsation? 01:57:04

A. It depends on the size of the IVC and things like that. But, yes, they certainly can.

Q. And, again, did Dr. McMeeking do any bench testing related to his calculations?

A. Can you repeat that? 01:57:27

Q. Did Dr. McMeeking do any bench testing related to his calculations?

A. No, he did not.

Q. Did your calculations using these assumptions differ from the analysis of stress and strain that Dr. McMeeking performed? 01:57:43

A. Yes, for all the reasons that we talked about.

Q. And did you prepare a demonstrative exhibit that illustrated the difference between the calculations you made using those assumptions and the calculations Dr. McMeeking made? 01:58:03

A. Yes, I did.

MR. NORTH: If we could bring up 7816, please.

BY MR. NORTH:

Q. Is this the demonstrative exhibit you created to illustrate the differences between your two calculations? 01:58:16

A. Yes, it is. 01:58:21

MR. NORTH: Your Honor, at this time we would tender 7816.

MR. O'CONNOR: No objection.

THE COURT: You may display it. 01:58:28

BY MR. NORTH:

Q. First of all, tell us what the significance is of the diagrams on the left of a perforated and not perforated filter.

A. Sure. This is showing results from the calculations from the finite element analysis I did. 01:58:52

So, again, we had the whole filter geometry. We have the IVC which is the blue region. We have the surrounding issues and we calculate the corresponding stresses and strains.

We can also visualize the deformed shape of the filter under these loads and that's what is shown here on the 01:59:08 left. This is showing the results of the finite element analysis and what the filter looks like after you deploy it into the IVC.

So on the left we have a non-perforated case. You can see the arms in the upper region and the legs sticking down 01:59:19 below. And particularly you'll notice that the arms are pushing the IVC out a little bit. It's bulging where the arms made contact.

And then in the perforated case, we've simulated what we call a fully perforated and, again, you can see under the 01:59:37

motions a bulging where the arms start to penetrate through. 01:59:40
Q. So did you do your calculations on the filter with the assumption that it was not perforated and then repeat the calculations with the assumptions that it was perforated?
A. Exactly. We looked at both conditions. 01:59:54
Q. And does the chart or the graph on the right of this 7816, does this demonstrate the difference in the test results or calculation results that you had compared to Dr. McMeeking?
A. Correct, exactly. What's shown in the bar graph on the right is for three different amounts of IVC motion. So the 02:00:15
first pair of bars is for one millimeter of motion so a small amount.
Q. I'm sorry if I could interrupt. What do you mean by motion in that context?
A. Sure. So this is how much the IVC is pulsing back and 02:00:28
forth, how much it's moving. So that's the motion again that we're talking about.
So we looked at one millimeter, we looked at 18 percent and a 50 percent pulsation so quite a lot of motion. And what is shown on the -- for each of the pairs of bars in 02:00:44
the red is, if you assume the values that Dr. McMeeking calculated, you get those corresponding strains whereas if you -- in the calculations that I did, where we're using the setup that I showed you, you get the blue bars. And so as you can see, the assumptions that were made by Dr. McMeeking had a 02:01:02

large influence on the results. 02:01:06
Q. Now, did Dr. McMeeking make an assumption having to do with the Nitinol wire beyond just a superelastic or not considering superelasticity? Was there something else about the wire that he considered? 02:01:40
A. Sure. Once we do these calculations, we can -- we compared the results or can compare the results to what is called the fatigue strength of the Nitinol which is basically how strong the material is, how much stress or strain it can tolerate. 02:01:54
And so Dr. McMeeking, for that fatigue strength of the material, used a value that came from medical literature rather than using data that was available from testing that had been done by Bard on its own wire.
Q. And why is that significant? 02:02:12
A. Sure. So the fatigue strength of Nitinol can depend highly on the way the material is processed and so utilizing a fatigue strength that was done on the wire that you're actually interested and that you're actually trying to assess is important so you capture all of that. 02:02:27
Q. Was that data available to him for the actual Nitinol wire if he wanted to use that in his calculations?
A. Yes, that was.
Q. And did you use that data?
A. In my calculations, those results do not come into play in 02:02:42

particular but we did reference them and discuss them. 02:02:45
Q. Now, did you also review some analysis that Dr. McMeeking did regarding tilt?
A. Yes, I did.
Q. And what was it that Dr. McMeeking did concerning tilt? 02:03:02
A. So Dr. McMeeking again did some analytical calculations and I apologize, analytical calculations are calculations kind of by hand, so writing out the equations. He also did some finite element analysis work regarding tilt.
Q. What assumptions did he use on the calculations that he did and in the finite element analysis he performed with regard to tilt? 02:03:26
A. So, again, he made several assumptions in the calculations that he did or -- didn't include various factors in the calculations. To summarize those, there were three main things. Number one, he assumed that the interaction between the filter and the IVC was frictionless so there was no friction of that interaction and we know friction obviously exists. 02:03:41
In addition, he modeled the IVC again as rigid which doesn't allow for deformation of the IVC or tenting where the filter arms poke in, again, as you can see here, which would resist tilting of the filter. 02:03:56
And, lastly, in the calculations he did, didn't look at the effect of incorporating the -- having the foot 02:04:16

disengaged from the wall. 02:04:21

Q. And with regard to tilt, did he do any actual bench testing of a Bard filter in coming to his conclusions?

A. No, he didn't.

Q. And with regard to tilt, does his analysis provide any information or data to determine how frequently Bard filters may tilt? 02:04:30

A. No. It wouldn't.

Q. Now, did you conduct your own analysis of tilt?

A. Yes, I did. 02:04:44

Q. Tell the members of the jury what you did to try to analyze tilt.

A. So, again, it was in a similar spirit to the calculations we talked about, used the same model setup as I used for the strain calculations. In this case we purposely displaced the tip of the filter, the cap, and looked at how much force it took to do that to get a sense of how easy it would be for it to tilt. 02:04:58

Q. And did you do any bench testing with regard to tilt?

A. Yes. We also did some bench testing again to validate the models that we had done. 02:05:15

Q. Did you prepare a demonstrative exhibit to demonstrate or explain the analysis you did with regard to tilt?

A. Yes, I did.

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MR. NORTH: If we could bring up 7702. 02:05:31

BY MR. NORTH:

Q. Is this the demonstrative exhibit concerning your tilt analysis?

A. Yes, it is. 02:05:46

MR. NORTH: Your Honor, we would tender 7702.

MR. O'CONNOR: No objection.

THE COURT: You may display.

MR. NORTH: Thank you, Your Honor.

BY MR. NORTH: 02:05:51

Q. Dr. Briant, can you explain to us what these two diagrams depict?

A. Sure. This shows the overall model setup. It's very similar to what we did before where we start off with the filter straight and displace the cap to the right and looked at 02:06:10 how much force it would take to do that.

Q. And what do you mean when you say both rigid and deformable IVC's analyzed?

A. That was part of looking at the validation work that we did, the experimental testing, and I prepared a demonstrative 02:06:25 for that as well.

Q. And that would show the bench testing that you did?

A. That's correct.

MR. NORTH: Could we bring up 7936, please.

Q. Is this the demonstrative that explains the bench testing 02:06:45

you performed regarding tilt? 02:06:48

A. Yes.

MR. NORTH: Your Honor, at this time we would tender 7936.

MR. O'CONNOR: No objection. 02:06:58

THE COURT: You may display.

BY MR. NORTH:

Q. Dr. Briant, tell us first what we're looking at on the left when we see this.

A. Sure. So what we're looking at is a picture of a filter 02:07:13 that we used for our laboratory testing; and the filter as you can see, is deployed into just a tube, that white PVC tube that we have there. And so we loaded this into what's called a tensile testing machine or an Instron machine. And we have a rod that is coming down from the tester. That is the silver 02:07:38 rod that you see coming down from the top in the middle. And it was -- it displaced downward and then we pushed on the tip of the filter in order to measure the force displacement response.

Q. So it's measuring the force of what? I'm sorry. 02:07:56

A. The force displacement. And that's what is shown on the graphs on the right. So we have the Recovery and the G2 filters, we did testing on both of those. And we did them in different sizes of tubes. We have 15 and 21 millimeters here. And so what we have is we come down on our machine and we did 02:08:14

all of this at 37 C, a temperature of 37 degrees Celsius, and we measured the force that is required to displace the cap. 02:08:18

And so our experimental data is shown by all of the blue lines and then we simulate those in our tests and -- sorry, in our models; and as you can see, we got very similar and good agreement between the models that we did in the testing. 02:08:38

I'll also mention, we didn't talk about it before but we did testing similar to this in terms of validating our strain calculations in terms of the bench testing that we did. 02:08:52

Q. Let me ask you this. Did it take more force or less force to tilt the G2 than it did the Recovery?

A. It took a little bit more force for the G2 compared to the Recovery.

Q. And what did this test suggest to you regarding Dr. McMeeking's analysis of tilt? 02:09:15

A. So the purpose of this test is to validate our model so we did our calculations. We want to make sure that our calculations are representative of reality. And so that is what -- that is what this testing is really motivated by, to demonstrate that our models can represent what's actually happening if you were to do this in real life. 02:09:32

So this goes to validates the calculations and the approach that we were using and the corresponding conclusions that I came up with. 02:09:47

Q. Did you -- in reviewing Dr. McMeeking's work, did he reach any other conclusions related to tilt? 02:09:54

A. Yes. So Dr. McMeeking made several claims regarding the role of tilt in this relation with perforation and strain in the filter. 02:10:09

Q. And are you critical of those findings?

A. Yes. I have some criticisms of those.

Q. And why? Tell us what those criticisms are.

A. Sure. So Dr. McMeeking made claims that if a filter tilts, it will necessarily perforate. That will directly lead to perforation and vice versa. He made the claim that if a filter perforates, it's going to tilt. And in addition, he made a claim that if a filter tilts, the strain is going to increase in the filter. 02:10:25

And so I did a series of calculations as well as review of the medical literature that demonstrate inconsistencies with those claims. 02:10:41

Q. And did you reach any opinion of Dr. McMeeking's conclusion that tilt increases the strain on the filter to the extent that it could lead to fracture of the filter? 02:11:04

A. I'm sorry. Could you repeat the question?

Q. Did you reach any opinion of Dr. McMeeking's conclusion that tilt increases a strain on the filter so as to lead to fracture?

MR. O'CONNOR: Objection, Your Honor. Irrelevant. 02:11:20

Can we approach for a minute? 02:11:23

THE COURT: Yes.

Feel free to stand up, ladies and gentlemen.

(At sidebar 2:11.)

MR. O'CONNOR: I don't think it's relevant or 02:11:48
appropriate for one expert to come in and just base all of his opinions criticizing another expert.

THE COURT: Why isn't that rebuttal evidence?

MR. O'CONNOR: Well, I mean, he's telling the jury how or who to believe. 02:12:04

THE COURT: Are you saying that one expert can't criticize the analysis of another expert?

MR. O'CONNOR: That's the limit of law. I don't think that's appropriate.

THE COURT: Based on what rule of evidence or what? 02:12:15

MR. O'CONNOR: It just seems to me like it's not relevant.

THE COURT: The flaws in the other expert's analysis are not relevant?

MR. O'CONNOR: Well, I think those are relevant but, 02:12:25
I mean, that's all he's talking about here today.

THE COURT: But it's relevant.

MR. O'CONNOR: Okay.

THE COURT: It seems to me that if one expert's analysis has flaws, the other side can point them out and 02:12:36

pointing them out is relevant to whether or not you believe the other side's experts. 02:12:39

MR. O'CONNOR: Okay.

THE COURT: Okay.

(End of sidebar discussion.) 02:12:47

BY MR. NORTH:

Q. Let me ask you this, Doctor. Did you reach any opinion yourself as to how tilt might increase or decrease the strain on the filter and whether that could lead to fracture?

A. Yes. So I performed calculations in addition to what we discussed before regarding strain in both a tilted and a non-tilted filter. 02:13:14

Q. And what did those calculations demonstrate?

A. Those calculations demonstrated that the -- in a tilted filter, that the strains -- we actually calculated slightly lower strains in a tilted filter. And this was in a G2 under the same conditions that we talked about previously compared to an untilted filter. 02:13:32

And this, again, is -- Dr. McMeeking claimed before that tilting, a filter will increase the strains in the filter considerably whereas the calculations with the complete IVC and the surrounding issues, you have about the same but a slight instruction in the strains. 02:13:49

Q. Did you see any evidence that Dr. McMeeking -- well, did he present any calculations in his report to support the 02:14:08

opinion that tilt leads to increased strain on the filter? 02:14:12
A. So Dr. McMeeking stated in his report that you would get an increase in strain but didn't actually present any calculations or produce any calculations to back up that claim.
Q. And did you prepare a demonstrative exhibit that reflects 02:14:28
your tests and calculations regarding whether tilt creases strain on a filter?
A. I did.
MR. NORTH: Could we bring up 7935, please.
BY MR. NORTH: 02:14:47
Q. Is this the demonstrative piece of evidence that you prepared?
A. Yes, it is.
MR. NORTH: We would tender 7935 as a demonstrative, Your Honor. 02:14:58
MR. O'CONNOR: No objection.
THE COURT: You may display it.
MR. NORTH: Thank you.
BY MR. NORTH:
Q. Tell us what this depicts, Dr. Briant. 02:15:09
A. Surely. This is, again, similar to what we were looking at before. We're looking at here the output from the finite element analysis that I performed. We're looking at the deformed shapes of the filter under load after it's been deployed into the IVC. And so the two right -- sorry, the two 02:15:23

left images are tilted filter. As you can see, it didn't tilt very much despite trying to tilt it in a non-perforated case. 02:15:27

And then on the right we have a perforated filter where you can see we tilted it over and allowed it to perforate and, again, pulsed the IVC and looked at the strains that result from when you have the tilted filter like this. 02:15:45

Q. And what does this mean over on the right, peak strain amplitude? What is that telling us here?

A. Sure. So what that is, that is the primary output from the model that we really care about. That's how much the strain is cycling back and forth every time the IVC pulses. That's what I was talking about, an amplitude, how much it's cycling. And what you can see in the numbers there on the bottom in the table are for -- on the next to the right most column, we have the not tilted results and then in the right column we have the tilted results. And, again, you can see the strains are lower in the tilted case. 02:16:03 02:16:19

Q. I'm sorry, the strain what?

A. The strains are lower in the tilted case.

Q. Did you come up with any hypothesis as to why that would be? 02:16:39

A. I expect it's likely due to additional stiffening that you would get when the filter is tilted. You can see in the tilted case how the arms, especially the one on left is straighter so it provided a stronger stiffening effect on the filter and 02:16:56

induced less bending. 02:17:01

Q. And was this test performed -- were these calculations or a bench test or both?

A. These were calculations.

Q. Do you have an opinion, based on this analysis, as to whether Dr. McMeeking's work on tilt provides an explanation for the leg fractures in Ms. Booker's filter? 02:17:17

A. So I don't think that Dr. McMeeking's work would provide an explanation for the leg fractures. And that's for two reasons. Number one is, all the results that we've talked about already and then it's the locations of the fractures that have been in Ms. Booker's filter were not the same as the high-strain points that Dr. McMeeking identified in his calculations. 02:17:36

Q. Did you also review Dr. McMeeking's criticism of Bard's testing of the filter and the development process? 02:17:59

A. I did.

Q. Have you developed, over the course of your career testing, protocols in your work with Exponent?

A. Yes. Testing of medical devices is a big part of what I do. 02:18:16

Q. What types of testing have you been involved with over the course of your career?

A. So it's a range of things. I do a lot of fatigue testing, again, where we're looking to analyze the fatigue performance 02:18:30

of the device and how much it can cycle back and forth. This is important for cardiovascular devices because you get cyclic loading either from the respiratory cycle as you will breathe or the pumping of the heart. Both of those can induce cyclic loading on devices. Also I've done tensile testing and other things like that. 02:18:32 02:18:46

Q. And what is your understanding of Dr. McMeeking's criticism of Bard's testing?

A. He was critical of it.

Q. And do you agree with his criticisms? 02:19:00

A. No. And for the reasons that we talked about that I mentioned early on. Dr. -- sorry, the testing was done by Bard, considered the relevant complications that are put forth by guidance documents from both the medical device community as well as from FDA that testing was performed. And in addition, Dr. McMeeking -- well, criticizing the work that Bard did didn't put forth any new ideas of his own or provide any alternative methods that Bard might have used during their testing. 02:19:18

Q. He say anything or do you have any comment about Bard's use or consideration of the superelastic nature of Nitinol in its testing? 02:19:35

A. Yes. So Dr. McMeeking, while reviewing Bard's FDA, criticized them for using superelastic properties for the Nitinol even though that's what the material actually is. 02:19:55

Using superelastic properties for Nitinol is certainly standard practice since that's what Nitinol does. 02:19:58

Q. And do you have -- did he have some criticisms regarding the pulsation rates used by Bard in its testing?

A. Yes. He was critical of them for using pulsations other than one millimeter. That is what was stated in his report as the pulsation that should be used, but Bard actually did testing analyses that were at one millimeter but also at larger than one millimeter. 02:20:12

Q. Did Bard do testing that took the filters all the way to a failure mode? 02:20:31

A. Yes. They did fatigue testing where they cycled the filter struts to the point at which they fracture, and this is important in order to be able to understand what material can actually tolerate, what it actually takes to break it. 02:20:44

Q. Is that standard testing to perform in developing a medical device?

A. Yes, it is.

Q. Did Dr. McMeeking offer any suggested alternative test protocols in his analysis? 02:21:01

A. No, he didn't.

Q. You also said I believe that your fourth opinion related to the Simon Nitinol filter; is that correct?

A. That's correct.

Q. Would you tell us that opinion again? 02:21:12

A. Sure. So the opinion is that the Simon Nitinol filter, from an engineering perspective, is not an alternative design because it lacks the functionality or benefit of being able to retrieve the filter. 02:21:14

Q. And what is the basis of your opinion? 02:21:32

A. The functionality of it and the benefit of being able to retrieve it. The two products are not the same if you can't do that.

Q. Dr. Briant, Dr. McMeeking described his work in this case as -- has described his work to be done to worst case conditions. What does that term mean in the engineering field? 02:21:45

A. Sure. When medical device companies are designing a product and making a product, it's important for them to understand the conditions that their device will be put into and to analyze and to test their device under aggressive conditions. So, essentially, it's sort of a foreseeable or realistic worst case that a device could see. 02:22:05

Q. Do you believe that Dr. McMeeking conducted his analysis to worst case conditions?

A. No. So Dr. McMeeking went beyond worst case and incorporated many assumptions, as we've talked about, that we know are just inaccurate and not correct such as making the IVC way stiffer than it actually is and other assumptions like that. So he went well beyond it and going beyond worst case isn't useful either. 02:22:21 02:22:41

Q. If Dr. McMeeking were to criticize your assumptions as best case as opposed to worst case, would you agree with that characterization? 02:22:42

A. Not at all. We used conservative assumptions all over the place in terms of the stiffness of the tissues. We looked at loading from three different ways that the IVC could be loaded from an internal pressure, from the whole thing being exceeded so we analyzed it from a bunch of different ways to try to bound the problem and use conservative assumptions. 02:22:55

Q. Did Dr. McMeeking, from what you've seen, do any kind of analysis specific to the events that Ms. Booker's filter experienced? 02:23:16

A. He did not.

Q. Explain that, please.

A. He didn't do any patient-specific analysis, didn't utilize any medical records or anything like that to analyze the stresses in the filter in this particular case. 02:23:26

Q. Other than his calculations and his computer modeling, have you seen any evidence of testing performed by Dr. McMeeking to support his opinions? 02:23:44

A. No. He didn't do any testing to support.

Q. In your experience consulting for medical device companies designing and developing new products, do you recommend to those companies that they design or manufacture a device based solely on calculations of the type performed by Dr. McMeeking? 02:24:02

A. No. As I mentioned, it's important to do testing of your device and in addition to the calculations that are performed. Calculations like these, these strain calculations, I mean they are a piece of the puzzle. They are part of a tapestry of data that you create when analyzing a device in order to assess its performance. 02:24:07 02:24:24

Q. In your analysis of Dr. McMeeking's work, did you see any evidence that he attempted to redesign the G2 filter to eliminate the risks he identified or otherwise come up with an alternative design? 02:24:41

A. No. He didn't put forth any alternative design changes.

Q. Thank you, Doctor. That's all the questions I have.

A. Thank you.

THE COURT: Cross-examination?

MR. NORTH: Oh, I'm sorry. Can I ask one quick question? 02:25:26

THE COURT: You can ask one follow-up question.

MR. NORTH: I'm sorry.

BY MR. NORTH:

Q. Doctor, are all of the opinions you've offered today here given to be a reasonable degree of engineering certainty? 02:25:33

A. Yes, they are.

Q. Thank you.

THE COURT: All right. Mr. O'Connor?

CROSS - EXAMINATION

BY MR. O'CONNOR:

Q. All right. Dr. Briant, how have you been? It has been, what about a year and a half since we met?

A. Something like that. 02:25:52

Q. Thanks for coming here today.

A. No problem.

Q. Now, you told us that your company doing work for the lawyers representing Bard has made $600,000; right?

A. Our bills over the course of the five years has totaled about $600,000. 02:26:08

Q. And in this case, what you've come here to tell the jury is your focus has been on the analysis and testing conducted by Dr. McMeeking; correct?

A. That has been the focus, yes. 02:26:25

Q. Your focus was not on what Bard did by way of analysis or testing in the design process; true?

A. So I did review to some degree the work that Bard did during their design process. We've talked about that. But the purpose of that was, again, to review the criticisms that Dr. McMeeking had made. 02:26:45

Q. All right. Well, just so you and I are on the same page, I wasn't at the deposition this last year, but didn't you say that your focus was not on testing or the analysis that Bard did in the design process? Your focus was on Dr. McMeeking; 02:26:58

right? 02:27:03

A. Yes. As I said, Dr. McMeeking made criticisms about what Bard did so I went back to review what Bard had done to understand the criticisms that he had made.

Q. Now, you do agree that a medical device company and the engineers that work for it should evaluate a device against the worst case analysis; correct? 02:27:13

A. It's important for device companies to understand the conditions for their devices and to analyze them under foreseeable worst case conditions, yes. 02:27:29

Q. And that's how medical device companies can predict how a device like a filter will perform and behave once it's out there; right?

A. It's part of the general assessment of a performance for a device. 02:27:50

Q. Well, certainly patient safety has to be number one for a medical device company; right?

A. Patient safety is certainly important, absolutely.

Q. And the reason engineers get involved is to make sure that the company knows that there are tests and ways to analyze a device to make sure it performs safely once it's released; true? 02:28:03

A. Companies strive to analyze their device under foreseeable worst case conditions to analyze it and understand it.

Q. And when you're saying foreseeable, really what has to 02:28:18

happen is that testing and analyses have to be developed that give companies like Bard some predictability about what the device is going to do once it's in a patient. Fair? 02:28:21

A. I would say that's fair. You want to understand what it's going to do, yes. 02:28:37

Q. And you know from all your work working for the attorneys for Bard that both the Recovery and G2 have failed out there in patients; right?

A. Yes. There have been complications in the field.

Q. You know that the G2 has caudally migrated downward; right? 02:28:55

A. Yes, I'm aware of that.

Q. And you know from your work that the G2 has tilted in many, many patients; correct?

A. I'm aware that it's tilted, yes. 02:29:13

Q. And you're aware that those filters that have tilted in many, many patients have perforated through the vena cava walls; correct?

A. I'm aware that perforation occurs, yes.

Q. And you're aware that in many, many patients that the G2 filter has tilted, has perforated and has fractured; correct? 02:29:26

A. I'm aware that fractures have occurred, yes.

Q. Did you receive Sheri Booker's records?

A. Not medical records, just expert records that were related to her. 02:29:46

Q. Do you know what happened to her? 02:29:47
A. Yes. She had an arm fracture, one leg fracture in two locations, and there was tilting and perforation.
Q. And a strut went to her heart. Were you aware of that?
A. I would have to go back and review. 02:29:59
Q. Something you weren't aware of, were you?
A. I don't recall it as I sit here right now.
Q. Well, that would be pretty important for you to know how this filter performed if you had accurate information about what happened to this patient, wouldn't it? 02:30:11
MR. NORTH: Objection, Your Honor. Argumentative.
THE COURT: Sustained.
We're going to take a break at this point. We're at 2:30. We will begin at 2:45, ladies and gentlemen.
(Jury departs at 2:30.) 02:30:22
THE COURT: Okay. Thank you.
(Recess at 2:30; resumed at 2:45.)
(Jury enters at 2:45.)
(Court was called to order by the courtroom deputy.)
THE COURT: Thank you. Please be seated. 02:46:13
COURTROOM DEPUTY: Mr. O'Connor, you may continue.
MR. O'CONNOR: Thank you.
BY MR. O'CONNOR:
Q. All right. Dr. Briant, I'm going to keep moving along here. You have the expertise to actually go in and the analyze 02:46:24

Bard's testing and assessments of the filter, don't you? 02:46:34
A. Yes, I have expertise in that area.
Q. I mean, if you were requested, you could have performed a more in-depth analysis of Bard's design testing and its finite element analysis of the Bard filters; true? 02:46:52
A. I could have review it more.
Q. But you weren't asked to do that?
A. I wasn't asked to do that, no.
Q. Bard has never come to you or its lawyers have never come to you and asked you, Dr. Briant, to form a root caught 02:47:03
analysis on why its filters were failing; true?
A. I'm sorry, did you say root cause analysis?
Q. Yes.
A. No, that hasn't been requested.
Q. True; correct? 02:47:18
A. Correct.
Q. You're certainly qualified to do one, though; right?
A. Root cause analysis is something that I do.
Q. So if requested, you could go through all the analysis and tell Bard why the filters are failing the way they have been; 02:47:29
true?
A. I could have gone through and looked at it and attempted it.
Q. But you didn't?
A. No, I did not. 02:47:37

Q. You have not done an analysis on Bard's filter fracture rates; correct? 02:47:38

A. No, I haven't.

Q. You have not communicated with any engineers at Bard; true? 02:47:46

A. Correct.

Q. You do not know what Bard's predicted failure rates were for the G2 at the time the filter was launched; correct?

A. No, I don't.

Q. And by the way, do you know -- are you aware that the G2 when it was first launched was a permanent filter? 02:47:57

A. My understanding is it was marketed or indicated for that use.

Q. And if it was marketed and launched as a permanent filter, that's what the Simon Nitinol filter was, was a permanent filter; correct? 02:48:18

A. The Simon Nitinol filter is a permanent filter.

Q. And in this case, do you know what Sheri Booker's filter was?

A. It was a G2. 02:48:29

Q. Do you know that she received it at the time that it was cleared as a permanent device?

A. I don't know that.

Q. You don't know whether the G2 exceeded Bard's predictability rates; is that correct? 02:48:45

A. No.
Q. True?
A. Correct.
Q. You never asked to look at that data, did you?
A. No, I didn't. 02:48:46
Q. And you don't have an opinion on what is an acceptable fracture rate for a filter, do you? 02:48:52
A. Correct, I don't have an opinion on that.
Q. And certainly you don't have an opinion whether the G2 is prone to fracture; correct? 02:49:13
A. I'm sorry. Can you repeat the question?
Q. You don't have an opinion one way or the other as to whether the G2 is prone or susceptible to fracture; true?
A. As a filter, no.
Q. You don't have that opinion? 02:49:23
A. Correct. Dr. McMeeking has that opinion and he bases it on analyses and I have criticism also of the analyses as we've talked about this whole time.
Q. But you haven't looked at that issue from your own analyses; correct? 02:49:35
A. So -- correct.
Q. Now, you do and have seen some internal communications among Bard personnel, haven't you? For example, at the deposition you and I met at you were shown an email from Dr. Ciavarella, the medical director. Do you remember that? 02:50:10

A. I don't remember the specific email but I have seen some, yes. 02:50:15

Q. And do you remember where Dr. Ciavarella noted that the Simon Nitinol filter didn't have complications but the G2 did? Do you recall that email that we talked about in 2016? 02:50:25

A. I recall the general email.

Q. And he was asking the question why wouldn't doctors want to use a Simon Nitinol filter as opposed to the G2? You recall that; right?

A. I recall that, yes. 02:50:36

Q. Dr. Briant, you do agree if a manufacturer like Bard has reason to be concerned about a potential complication, it should address the complication before releasing the device to the market; correct?

A. I think they should do testing to evaluate their devices. 02:51:01

Q. Before it's released; true?

A. Yes. They should do testing before a device is put on the market.

Q. And that is certainly true if a company like Bard has reason to know that its filter may fail once it is released to the market; correct? 02:51:15

A. Correct. If there are complications known, they should look at it.

Q. Now, you have never looked at any Bard filters positioned in the IVC filter through imaging; correct? 02:51:33

A. Just what's in medical literature. 02:51:36
Q. You've never looked at individual imaging of patients to see if that diagram you did where the filter was perforating on each side of the vena cava wall was, in fact, a realistic condition, have you? 02:51:53
A. Well, I've seen, through my review of the medical literature, numerous pictures of filters in the IVC.
Q. As it relates to the Bard filters, though, the ones that you have seen perforated have been filters that tilted; correct? 02:52:07
A. I don't think that that is necessarily true.
Q. Well, you have seen that, though, haven't you?
A. That if a filter is perforated, it's also tilted?
Q. Yes.
A. I've seen images of that. 02:52:17
Q. And you do agree that a leg that perforates through the vena cava wall can lead to additional tilting? You agree with that concept, don't you?
A. I think that it could but it doesn't necessarily mean that it does. 02:52:37
Q. But it's something you haven't ruled out; fair?
A. I wouldn't say I've ruled it out. As I said, I think it could but it doesn't necessarily mean that it does.
Q. Now, let me just ask you a question about linear and superelastic. Isn't it true that Dr. McMeeking used linear 02:52:55

because -- or for small strains and small increments of strains? 02:52:59

A. He used linear elastic in his strain calculations.

Q. And when engineers like you go and do these calculations, doesn't linear apply first before superelastic? 02:53:14

A. Not if the material is made of superelastic.

Q. Dr. McMeeking looked at articles, too, about the dynamics of the anatomy; correct?

A. I think he reviewed those, yes.

Q. He looked at things such as Murphy and Laborda; true? 02:53:36

A. Correct, yes.

Q. And he had looked at Laborda which talked about the IVC filter and suggested that filters do not resist motions of the IVC wall. Do you recall -- you've seen that article as well; true? 02:53:58

A. I've seen that article and it shows that the IVC filters that they studied resisted the motion of the IVC wall.

Q. All right. But you have not seen any studies related to the G2; correct?

A. Correct. The G2 was not used in that study. 02:54:12

Q. And what you do know about the G2 is that it's known to caudally migrate; correct?

A. Caudal migration occurs, yes.

Q. Meaning it separates itself from the vena cava wall?

A. I don't know if I would say separates itself but it 02:54:24

travels downward. 02:54:26

Q. And you do understand how that can lead to complications such as tilt; fair?

A. I think it could lead to tilt, yes.

Q. And then of course while you can't rule it out, you can envision scenarios where tilt will lead to other complications including perforation; correct? 02:54:34

A. I think that it could but, again, I don't think it necessarily does and I think there are other conditions that come into play. 02:54:51

Q. But you haven't done any testing one way or the other to rule that in or out. Fair?

A. That tilt leads to perforation?

Q. Yes.

A. So I did work in my calculations where we looked at the forces that filter stress applied to the IVC at a variety of different diameters. So we looked at large diameters, medium diameters, and small diameter IVCs. And the forces that the filter struts apply obviously go up as you decrease the diameter of the IVC. You have to squish the filter down more. 02:55:00 02:55:22 It puts on more force.

Studies have also shown, though, with filters in them that have not shown any correlation between IVC diameter and increased perforation rate. So, again, changes in force I don't think necessarily corresponds with perforation. 02:55:37

Q. Now, I thought I heard you say that in the worst case scenario you think Dr. McMeeking went too far; right? 02:55:40

A. Yes. I think he went beyond the worst case.

Q. But you haven't seen any internal documents from Bard reflecting how many failure modes Bard's been aware of that have occurred out there in patients, have you? 02:55:53

A. I'm sorry. Could you repeat that?

Q. Sure. You haven't seen internal documents about what Bard knew about how many patients were having failed filters, G2s?

A. That's correct, I haven't seen that. 02:56:10

Q. And what Dr. McMeeking's calculations predicted is that the G2 filter would fail; true?

A. Dr. McMeeking says that his calculations indicate the G2 filter is prone to failure and, obviously, I disagree with that for all the reasons that we've talked about. 02:56:27

Q. But certainly depending on what's happening out there in the real world and if patients like Sheri Booker have had a filter, G2, that migrated, tilted, perforated, and fractured, then Dr. McMeeking was looking at those type of failure modes when he did his calculations; right? 02:56:47

A. I don't think that's true. I don't think that the calculations that Dr. McMeeking did necessarily showed what happened in any one particular patient.

Q. But he was addressing failure modes that could occur because of the design; correct? 02:57:01

A. He was calculating the strains in the filter just like I did. 02:57:03

Q. And looking at how they would manifest into failure modes. Fair?

A. And then comparing those to the fatigue strength, yes. 02:57:11

Q. And in terms of to what extent they have occurred out there, that certainly is significant on what the worst case scenarios are in patients; true?

A. I'm sorry. Could you repeat that?

Q. Sure. The fact that they are failing out there means that's something, going back in time, Bard engineers should have taken steps tested to predict; right? 02:57:26

A. Well, I think that one tries to understand the environment that you're going to put a medical device in to the best of your abilities and do testing accordingly. 02:57:39

Q. And if they don't understand the anatomical environment at the time they are testing the filter, that will put patients' safety at risk; correct?

A. I think that you should try to understand it as best you can. It is absolutely true that our understanding in the medical device community, IVC has improved over the time over the years. 02:57:52

Q. Well, I'm talking back in time of the G2. You agree that if a medical device company doesn't have a good understanding of the anatomy and the physiology where a device is going to be 02:58:10

implanted, that can impact patient safety. You agree with that; true? 02:58:14

A. Again, I think that a company should try to understand to the best of your abilities through imaging or medical literature review, however they can. 02:58:25

Q. Patient safety should always come first, yes?

A. It should absolutely be.

Q. And meaning it's important to understand the anatomy, true?

A. Yes. 02:58:35

MR. O'CONNOR: That's all I have.

THE COURT: Redirect?

MR. NORTH: Nothing further, Your Honor.

THE COURT: Okay. Thank you, sir. You can step down. 02:58:41

(Witness excused.)

MR. NORTH: Your Honor, at this time we would recall Mr. Rob Carr to the stand.

THE COURT: All right.

Mr. Carr, you're still under oath for purposes of the trial so you can come directly back to the witness stand. 02:59:26

(ROBERT M. CARR, JR., a witness herein, was previously duly sworn or affirmed.)

DIRECT EXAMINATION

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BY MR. NORTH: 02:59:52

Q. Good afternoon, Mr. Carr.

A. Good afternoon.

Q. I don't want to repeat a lot of the background information that you have testified to last week but can you just briefly 02:59:57 tell us your educational background?

A. I have a bachelor's in biomedical engineering from the Catholic University of America.

Q. And what sort of courses made up your major in biomedical engineering? 03:00:15

A. All your mechanical engineering classes as well as some nursing type classes.

Q. Has most of your professional career since college been involved with medical devices?

A. Yes, all of it. 03:00:29

Q. What was your first job after graduating from college in the biomedical engineering field?

A. I worked for a start-up in Boston called Organogenesis. That was a company that developed products from collagen which is a protein in your body. 03:00:45

Q. And what were those products designed to treat?

A. We had a vascular graft which was a surgical device. We had a living skin equivalent which we sold to cosmetic companies to do testing on as well as some hernia repair devices. 03:01:06

Q. And what was your next job after Organogenesis? 03:01:13
A. I worked for Nitinol Medical Technologies.
Q. And is that also known as NMT?
A. Yes, it is.
Q. And when did you join that company? 03:01:25
A. 1996.
Q. And what positions did you hold with that company?
A. I had various R&D level positions and ended up as the director of R&D, Research and Development.
Q. And what product did you spend most of your time on at NMT? 03:01:42
A. Filters.
Q. When you started working with IVC filters in the 1990s, what type of filters were available?
A. They were just permanent devices available. 03:01:58
Q. And when you first started working with IVC filters, did you have the opportunity to work with Dr. Morris Simon?
A. Yes, his office was right next to mine.
Q. And who was Dr. Simon?
A. Dr. Simon was a pioneer in interventional radiology. His 03:02:13
interests were in imaging as well as in vena cava filters.
Q. And what was his role in the development of the Simon Nitinol filter?
A. He was instrumental in the design of it. He and a group of engineers worked on developing that device. 03:02:35

Q. Did you eventually start to work with Dr. Simon on developing a retrievable IVC filter? 03:02:41

A. Yes, we did.

Q. And why were you and Dr. Simon working on a different sort of filter when you already had the Simon Nitinol filter on the market? 03:02:56

A. Dr. Simon in particular realized that if you could make a vena cava filter that could be removed at any time, then that would treat an entirely new patient population, people who at that time really couldn't get a vena cava filter to help them if they were permanently implanted. That treated a subset of patients when they really were a whole other set of patients who deserved to be able to get a filter. 03:03:19

Q. Were you and Dr. Simon, and your entire team at NMT, passionate about the possibility of developing a retrievable filter? 03:03:40

A. Yes. It was a very exciting opportunity. It had never been done and we were really proud once we accomplished it.

Q. Are there aspects of the inferior vena cava itself that make designing an implantable device for that vessel challenging? 03:04:02

A. Sure.

Q. And can you tell us what some of those are?

A. It's a dynamic vessel. It has flow into the heart so it's a pretty big vessel and it sits just below the renal veins or 03:04:18

the veins that go to your kidneys, so there's flow things you need to take care of and it moves a little bit. 03:04:25

Q. Is there a potential for flattening in the inferior vena cava?

A. Yes. 03:04:39

Q. What about expansion?

A. Yes.

Q. And what about stretching?

A. Yes.

Q. What are some of the challenges on developing a long-term retrievable filter that you and your team faced? 03:04:45

A. Mostly was being able to remove it and to us the most important thing was after the patient no longer needed it. So that means that there wasn't a particular time frame. It wasn't 30 days or 40 days or 50 days that everybody needs a filter. Everybody is different and so our goal was to design something that could be removed when you, the individual, didn't need it any more. 03:05:10

Q. Were there any particular challenges with developing the hooks or the anchoring mechanism for the filter? 03:05:27

A. Yes. So one of the major things to consider is when you -- these devices become incorporated into the wall of the vena cava, and once they become incorporated and you intend to remove it, you have to be able to remove it without doing sufficient damage to that wall. 03:05:48

Q. And what about the thickness of the arms and legs? Are there particular challenges in designing a retrievable filter with that aspect? 03:05:51

A. Yes. There's a balance between the size of the filter and then these are delivered through a small tube called percutaneously and so you want to make that tube as small as possible also. 03:06:04

Q. Are there challenges in designing a retrievable filter particular to the width of the legs?

A. Yes. And it's the same sort of reason. The larger the device, the larger the tube it needs to go through and that can cause different complications unto itself. 03:06:21

Q. How did you and the others at NMT with whom you worked address and tackle those challenges?

A. Through a lot of trial and error, through a lot of prototypes. We talked to a lot of physicians. Having Dr. Simon there was an incredible benefit as well as the other physicians that we worked with in the Boston area who were passionate about filters. We did a tremendous amount of testing and, like I said, a lot of trial and error. 03:06:43 03:07:08

Q. In addition to Dr. Simon, were there a couple of other medical doctors that you worked closely with in the development of the first retrievable filter?

A. Yes. Primarily John Kaufman who was at Mass General Hospital at the time and Tony Venbrux who was at Johns Hopkins 03:07:27

at the time. 03:07:34

Q. And what were their roles in helping to develop the Recovery filter?

A. Consultative as well as Dr. Kaufman was just down the street from our office so he was involved on a pretty often basis. He would come see the testing we were designing. He would do the animal labs with a lot of the filters, prototypes that we would test prior to the ultimate design. And Dr. Venbrux was involved in all the animal testing as well. 03:07:43

Q. And you mentioned Dr. Kaufman's affiliation. Where was Dr. Venbrux affiliated with at the time? 03:08:06

A. He was at Johns Hopkins at the time.

Q. At some point did NMT sell its rights to the Recovery filter as well as the Simon Nitinol filter to C.R. Bard?

A. Yes. In late 2001. 03:08:24

Q. And you eventually moved to Bard?

A. I did, in July of 2002.

Q. And why did you decide to move to Bard, Mr. Carr?

A. A lot of reasons. The opportunity to work for a larger company with clearly more career advancement opportunities. 03:08:40 Bard had a history of very significant product innovation. The people that I worked with who were at Bard at the time I enjoyed working with very much. And then personally it kind of all worked out. Our kids were about to start kindergarten. My wife had graduated school and so it was just a good time. 03:09:06

Q. And when you moved to Bard, did you have an opportunity to continue working with IVC filters? 03:09:11

A. Yes. When I moved to Bard, I ran our IVC filter as well as our angioplasty and biopsy development.

Q. And what was your position when you first moved to Bard? 03:09:26

A. It was a director of R&D.

Q. And did any of your other colleagues from NMT move with you, either before you or after you, to Bard also?

A. About a year later I brought one of our engineers, Andrzej Chanduszko. 03:09:49

Q. And is Mr. Chanduszko still with the company today?

A. He is.

Q. When you came over to Bard, did you continue to work with Dr. Venbrux and Dr. Kaufman?

A. Yes, we did. 03:09:59

Q. Let's talk about the development of a new medical device.

MR. NORTH: Would you pull up 6089, please. And if we could go to the second slide.

BY MR. NORTH:

Q. Did you put together a demonstrative exhibit that explains the development process for a new medical device? 03:10:40

A. Yes.

Q. And was this personally prepared by you?

A. Yes.

\\\

MR. NORTH: At this time I would tender 6089. 03:10:55

MR. LOPEZ: As a demonstrative, it's fine, Your Honor.

THE COURT: All right. You may display it.

BY MR. NORTH: 03:11:11

Q. Does this set forth the general points that you are covering as far as a new product development process?

A. Yes.

Q. If we could display the next slide. Explain for us what the new product development process involves in creating a new 03:11:27 medical device.

A. So our process is similar to most companies in our field where we break it down into phases; and at each of those phases there are what we call design reviews, or some people call them stage gate reviews, where more senior people would review the 03:11:48 work to be done and then either approve or have questions for the product development team. And so our phases of development are what we call idea generation which is fairly self-explanatory. It's a phase where we develop different ideas based on user needs and so user needs that, be they 03:12:18 patients or physicians, that are unmet, so we collect those ideas.

Q. Let's move to the next slide. I think it talks more about that.

A. I believe one more. 03:12:34

Q. And then let's go to the next slide if we could. 03:12:34
A. So like I was saying, those unmet needs we develop then hypotheses for how we can solve those needs or can we provide a solution to them, be they a technical one if it's something we could never overcome we pass on it probably. If it's something 03:12:52
we have ideas around, we would then develop a business case for a potential project which we call a POA or a product opportunity assessment.
Q. And let's go to the next slide if we could. What is a concept phase? 03:13:09
A. It's a next step of literally developing prototypes, trying to learn as much as we can about the use environment and then kind of honing down hopefully multiple set of different devices that were then be honed down into potential solutions.
MR. NORTH: Next slide, please. 03:13:36
Q. And are there various steps that have to be undertaken as part of the concept phase?
A. Yes. We develop a lot of documents. The design and development plan is an outline for the project itself. I spoke a minute ago of product opportunity assessment which is a 03:13:53
business document. We do a design input summary which is a summary of all of the things we've learned up to that point, a risk assessment and a DFMEA as well as a draft of potential specifications.
Q. Let's move to the next slide. 03:14:15

Do various different groups within the medical device company get involved in the concept phase, development? 03:14:20

A. Yes. Our teams are multi-disciplined and always involve these four groups which is marketing, research and development, quality, and regulatory and may involve other groups in the company as well. 03:14:36

Q. Let's go to the next slide and then the next slide. What is the purpose of the feasibility phase?

A. It's to further test your designs to see if they will ultimately meet your specifications to fine-tune your specifications, to develop draft labeling, packaging, those sorts of things and also develop any new test methods that are going to be necessary in your next stage which is verification. 03:14:55

MR. NORTH: And the next slide, please. And the next slide. 03:15:17

Q. What is the development phase for a new medical device?

A. It's called a development or qualification phase in a lot of places where you do testing to verify and validate that your output, the design -- that you have met your design input requirements. 03:15:39

Q. And the next slide, it's final stage launch, post launch.

A. Is I think self-explanatory. In a pre-launch, that's usually your regulatory phase and then once the device is launched, there's a post-launch phase which involves complaint handling and active things. 03:16:00

Q. Now, when the G2 Filter was being developed, was this general product development cycle followed? 03:16:10

A. Yes.

Q. And was it generally followed for the Recovery filter also? 03:16:21

A. Yes.

Q. Mr. Carr, do you know approximately how much money has been spent by Bard over the years in research and development with filters?

MR. LOPEZ: Your Honor, foundation. 03:16:39

THE COURT: Sustained. I think you need to lay foundation for that.

BY MR. NORTH:

Q. Have you been involved extensively with the development of research -- well, development of filters over the years -- 03:16:48

A. Yes.

Q. -- at Bard?

And has that been in the -- as a part of the research and development department of the company?

A. Yes. 03:16:59

Q. And at times have you -- many of the times have you been the director of the company -- I mean of that department?

A. Yes.

Q. Are you generally familiar with the budgets and expenditures of the department in research and development? 03:17:10

A. Yes. 03:17:14
Q. And have you been -- do you have access to the information in the business records of the company that show you how much money has been spent in research and development over the years with IVC filters? 03:17:27
A. Yes.
MR. NORTH: Your Honor --
THE COURT: Go ahead and ask your question and see if there's an objection.
BY MR. NORTH: 03:17:35
Q. Based upon your position, your knowledge and your familiarity, do you have -- do you know how much the company has spent over the years in research and development for IVC filters?
A. Yes. 03:17:49
MR. LOPEZ: Sorry. Your Honor. That's not the question I guess I need to object to.
THE COURT: So you didn't object to the one that was just asked.
MR. LOPEZ: Well, I'm going to object to foundation 03:17:59
and then speculation and the hearsay. That information can only be based on documents that we don't have.
THE COURT: Overruled.
BY MR. NORTH:
A. Yes. 03:18:14

Q. And can you tell the members of the jury how much money has been spent by the company in research and development with inferior vena cava filters? 03:18:15

MR. LOPEZ: Same objection, Your Honor, as well as best evidence and hearsay, foundation. 03:18:24

THE COURT: Overruled.

THE WITNESS: About $18 million.

BY MR. NORTH:

Q. Now, over the years have you worked closely with the Marketing Department as well as activities regarding the filters? 03:18:38

A. Yes.

Q. And many times did you partner with people in the Marketing Department on various initiatives and meeting with doctors and conducting clinics, training, things of that nature regarding filters? 03:18:49

A. Yes.

Q. And are you currently a Vice President of Bard Peripheral Vascular?

A. Yes. 03:19:00

Q. And do you sit on the management board of the company?

A. Yes, I do.

Q. And in that role, do you have access to the budget information and expenditures of other departments in the company? 03:19:12

A. Yes.
Q. And based upon your familiarity and your access to the data, do you know, happen to know how much money has been spent over the years by the company in the marketing of inferior vena cava filters? 03:19:12 03:19:26
A. About $6 million.
Q. Now, did you begin with NMT in 1996?
A. Yes.
Q. And was the Recovery filter already under development at that time? 03:19:47
A. Yes.
Q. Do you know when development had started on the Recovery filter?
A. Not exactly, no, but prior to that.
Q. While you were at NMT, did the company develop a number of prototypes for the retrievable filter? 03:20:03
A. Yes, many.
Q. And tell us why some of the prototypes were rejected or not used.
A. Well, ultimately they were all rejected until the final one because they didn't pass one test or another along the development cycle. 03:20:18
Some were removed from consideration very quickly and others made it all the way to animal studies and failed there. So different ones for different reasons. 03:20:37

Q. When was the initial design of what ultimately became the Recovery filter created or invented? 03:20:41

A. In 1998 time frame.

Q. Once that initial design was conceptualized, what did you do next? 03:20:59

A. We built some and then we tested them both in the bench and in the animals.

Q. And what is the purpose of bench testing?

A. Well, there's a guidance document for vena cava filters of tests that you need to do to satisfy your regulatory filing, so of course we did those. And then once you get past those, we put them in animals. Some of the things we were trying to test couldn't really be done on a bench so we would use animal models to test those things. 03:21:19

Q. Did your testing include a bench test for fatigue testing? 03:21:39

A. Yes. That's one of them.

Q. And did your bench testing include a test for migration resistance?

A. Yes.

Q. What type of animal tests did the company perform? 03:21:51

A. We did two different types of tests. We called one acute or chronic or longer term. The acute testing was really to test the deployment or the placement of the filter, how accurately could it be deployed, could you deploy it at all, centering of the device whereas the chronic or the longer term 03:22:14

set of animals was to test the removability of the filter and any damage to the vena cava that might have happened. 03:22:21

Q. Did Drs. Kaufman and Venbrux participate in that animal testing?

A. Yes, they did. 03:22:38

Q. And are animal studies fairly typical in the industry?

A. Yes, when needed.

Q. Did the company also conduct a clinical study regarding the Recovery filter?

A. Yes. We did a special access study in Canada. 03:22:51

Q. And did that involve Dr. Murray Asch?

A. Yes.

Q. In your experience in the industry, are clinical studies as common for these types of medical devices?

A. At the time they were not but since they have become common for optional filters. 03:23:08

Q. Let's talk about the fatigue testing if we could.

MR. NORTH: And let's pull up Exhibit 5022.

BY MR. NORTH:

Q. Do you recognize 5022? 03:23:49

A. Yes. It's a lab notebook from NMT.

Q. Now, when Bard took over the -- or bought the rights to the Recovery filter and the Simon Nitinol filter, did the development materials for the filters, those products, get transferred to Bard from NMT at that time? 03:24:08

A. Yes.
Q. And did the development materials, including the testing materials, then were those maintained as a part of Bard's business records?
A. Yes. 03:24:23
Q. What is the date or date range for this laboratory notebook from NMT? Can you tell?
A. 6-30-99.
Q. And whose laboratory notebook was this?
A. Andrzej Chanduszko. 03:24:38
Q. Now, did Mr. Chanduszko work under your direction while at NMT?
A. Yes.
Q. And then when he came to Bard, did he work under your direction? 03:24:52
A. Yes.
Q. So if Mr. Chanduszko was conducting bench testing in 1999 at NMT on the Recovery filter, would that have been generally under your supervision?
A. Yes. 03:25:08
Q. And would you have had had access to his laboratory notebooks?
A. Yes.
Q. And would those notebooks have been maintained in the regular course of business for first NMT and then later Bard? 03:25:15

A. Yes.

MR. NORTH: Your Honor, at this time we would tender Exhibit 5022.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted. 03:25:26

(Exhibit Number 5022 was admitted into evidence.)

MR. NORTH: May we display, Your Honor?

THE COURT: Yes.

MR. NORTH: If we could turn to the second page, please. 03:25:45

BY MR. NORTH:

Q. Does this indicate generally when the fatigue testing -- or let me ask you this first: Does this laboratory notebook concern fatigue testing?

A. Yes. 03:25:57

Q. And does it indicate the general time period when the testing began?

A. Yes, June 30, '99, or July 1.

Q. And then if we could go to page 142, looking that the top, does this give you some indication as to how long a period this testing lasted? 03:26:20

A. Yes. Until February 10, 2000, February 11. Sorry.

Q. According to your review of the laboratory notebook and your familiarity with that test, do you know approximately how many times the Recovery filter was cycled in the fatigue test 03:26:43

and that was documented in this notebook? 03:26:48

A. Around 417 million.

Q. And what does that mean to cycle the filter 417 million times as a part of this test over that eight-month period?

A. So it's -- to fatigue it is to move it, compress it, and 03:27:08 expand it or let it return to its normal diameter for -- just to keep doing that literally for 417 million times.

Q. Let's talk a moment about migration-resistance testing.

MR. NORTH: If we could pull up 5017.

Q. Do you recognize 5017? 03:27:51

A. Yes.

Q. And what is this?

A. It's a design verification report for the Recovery migration study.

Q. And was this conducted at NMT? 03:28:01

A. Yes.

Q. In what time period generally?

A. It looks like August 1999.

Q. And did Mr. Chanduszko participate in this testing?

A. He's listed as an approver. 03:28:20

Q. And were you familiar with this test being performed and the results while you were at NMT?

A. Yes.

Q. And were you familiar with this document while at NMT?

A. Yes. 03:28:29

Q. And was this document maintained in the regular course of NMT's business? 03:28:30

A. Yes.

Q. And would this have been part of the materials that were transferred to Bard when Bard acquired the rights to the product? 03:28:39

A. Yes.

MR. NORTH: Your Honor, at this time I would tender 5017.

MR. LOPEZ: No objection, Your Honor. 03:28:49

THE COURT: Admitted.

(Exhibit Number 5017 was admitted into evidence.)

BY MR. NORTH:

Q. What was the purpose of the migration-resistance testing?

A. To determine the pressure at which the vena cava filter would move due to a clot burden. 03:29:01

Q. And for this testing, did you assume or utilize different diameter mock inferior vena cavas?

A. Yes.

Q. And do you recall what those were? 03:29:20

A. 28, 15 and I don't remember in between sizes.

Q. And you, obviously, weren't testing these on human beings. This was a bench test. So what sort of mechanism or machine did you use to actually test the migration resistance?

A. We built a system to test them which consisted of a flow 03:29:46

loop and then an area that we could implant the filter and we used a sausage casing material to try and simulate the vena cave where we would place the filter and then we would -- had a recirculating bath and would use a different piece of sausage casing to try and occlude the filter and, therefore, stop flow and create a pressure underneath and record the pressure at which the filter moved. 03:29:52 03:30:13

Q. And why did you use sausage casing?

A. Well chose it to implant the filter into it because it was a natural material and it was available at the time. 03:30:34

Q. And why did you choose the 15 millimeter and 28 millimeter diameters as the parameters to test?

A. We chose 15 as the lower boundary of vena cava sizes and 28 was our maximum indicated diameter size.

Q. Were those spelled out in the FDA guidance document? 03:31:00

A. To test your maximum diameter is spelled out.

MR. NORTH: If we could bring up 5126 which I believe is already in evidence. I believe it's already in evidence.

COURTROOM DEPUTY: Yes, it's admitted.

THE COURT: You may. 03:31:45

BY MR. NORTH:

Q. Let's turn to page six if we could. Under number five, caval perforation, filter migration, first of all, are you familiar with the FDA guidance?

A. Yes. 03:32:07

Q. What does the guidance say about the test for migration resistance? 03:32:07

A. It says this test should demonstrate that the filter fixes itself within the vena cava at the deployment site and undergoes sufficient endotheliolization. The force necessary for device fixation should be characterized over the range of labeled inferior vena cava diameters. In addition, this force should not suggest a tendency to perforate the caval wall. 03:32:19

Q. Is that reference to the range of labeled inferior vena cava diameters that led to the selection of the 28 -- 15 and 28 millimeter parameters? 03:32:40

A. Yes.

Q. Now, how were you able to determine -- in conducting this migration-resistant testing, how was the team at NMT able to determine whether it passed the test, the filter? 03:33:16

A. We have an acceptance criteria that it passed.

Q. And what was the acceptance criteria for the filter, for that migration-resistance testing?

A. It was 50 millimeters of mercury at the 28 millimeter diameter. 03:33:36

Q. Now, was that an absolute pass/fail number or was are it a mean for the test?

A. It's a mean.

Q. And explain to the jury what that means in that context.

A. The mean of a population is the average, if you will, of 03:33:53

the populations. 03:33:56

Q. Was that the only migration resistance test that NMT or Bard conducted?

A. No.

MR. NORTH: If we could bring up Exhibit 5232. 03:34:24

BY MR. NORTH:

Q. Do you do recognize this document?

A. Yes.

Q. And what is this document?

A. It's the study of our process -- after our process validation. 03:34:34

Q. And what is process validation?

A. Do you make the product as it was intended to be made? So do you follow all the instructions? And is what you made what you intended to have done? 03:34:53

Q. And I see that you were supposed to be -- provide a signature of approval on this particular test report?

A. Yes.

Q. And was this test conducted by Mr. Chanduszko?

A. I think he wrote the protocol. I don't know if he did the test. 03:35:09

Q. Did you review this test report when it was completed?

A. I'm sure that I did.

Q. Do you know why this particular version is not signed?

A. No, I don't. 03:35:24

Q. Have you reviewed this defendant report? 03:35:30
A. Not in a while.
MR. LOPEZ: Your Honor, not going to object -- if he's laying a foundation, I'm not going to object to the admission of this documents. 03:35:38
THE COURT: All right.
MR. NORTH: We'll tender for admission 5232, Your Honor.
THE COURT: Admitted.
(Exhibit Number 5232 was admitted into evidence.) 03:35:46
BY MR. NORTH:
Q. And what were the general results of that testing, do you recall?
A. I can't see it. Sorry.
Q. Did Bard also continue to perform migration testing after it began selling the Recovery filter? 03:36:10
A. Yes.
MR. NORTH: If we could show 5526.
BY MR. NORTH:
Q. Do you recognize this particular document? 03:36:35
A. Yes.
Q. And what is this, Mr. Carr?
A. It's a characterization test of another migration test.
MR. NORTH: Your Honor, we would tender for admission 5526. 03:36:51

MR. LOPEZ: No objection, Your Honor. 03:36:54

THE COURT: Admitted.

(Exhibit Number 5526 was admitted into evidence.)

MR. NORTH: Let's look at page nine and display that to the jury. 03:37:03

BY MR. NORTH:

Q. What were the acceptance criteria for this particular test?

A. There weren't any. It was just a comparative test.

Q. And what is the significance of not having acceptance criteria? 03:37:32

A. It was just to compare. It was for information.

Q. And what was the purpose of conducting competitive migration testing?

A. To learn -- to get more information about how filters were performing. 03:37:57

Q. Well, I guess what I'm asking is with the word "competitive" in the title, what were you comparing the Recovery filter against?

A. Other vena cava filters. 03:38:10

Q. And if we could look at 5252. Do you recognize 5252?

A. Yes.

Q. And what is this?

A. This is the test we were talking about.

Q. And do you recall what filters you were comparing the 03:38:44

Recovery filter to? 03:38:46

A. We compared it to the available filters on the market at the time.

MR. NORTH: Your Honor, at this time we would tender 5252. 03:38:58

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

MR. NORTH: If we could display to the jury.

THE COURT: You may.

MR. NORTH: Page 12, please. 03:39:05

(Exhibit Number 5252 was admitted into evidence.)

BY MR. NORTH:

Q. What was the conclusion?

A. The conclusion was that the migration resistance of the Recovery filter appeared comparable to the Günther Tulip, which 03:39:26 is another removable filter, throughout all simulated IVC diameters. And the other filters seemed to have a higher -- a greater resistance to migration in comparison to the Recovery filter, the Günther Tulip.

Q. Were the other filters that it was compared to permanent 03:39:46 filters?

A. Yes, with the exception of the OptEase which is also a short-term optional filter.

Q. What do you mean by short-term optional filter?

A. It has a very short window of the time that it can be 03:40:00

removed. I believe it's in the 12-day time frame. 03:40:04
Q. Did the Recovery filter -- when the test was run properly, was the migration resistance above 50 millimeters of mercury for that filter?
A. Yes. 03:40:21
Q. And the second paragraph on that same page, there's a reference to a large amount of test variation.
A. Yes.
Q. What was the circumstance that led to that, if you recall?
A. So we observed a greater variation than we had seen in our 03:40:43
previous testing, meaning that the data wasn't as centered as it had been prior. So we did an investigation to find out why -- if something had changed in the test or the person doing it or whatever it was and we came up with the following, that they were introducing more than one piece at a time which is 03:41:09
not how the test is done. And also to create more of a layer where the filter itself could implant so by creating more than one layer of sausage casing.
Q. Now, was this in the earlier days of the time period after Bard had acquired the rights to the Recovery filter? 03:41:31
A. Yes.
Q. And had Bard begun to manufacture the Recovery filter at one of its own facilities?
A. Yes. The manufacturing was moved from NMT to Glens Falls, New York. 03:41:48

Q. And when you say to Glens Falls, New York, is that a Bard facility there? 03:41:49

A. Yes, sorry. It's an operations facility.

Q. So did your team conduct a test to try to compare filters manufactured at Bard to the performance of filters that had previously been manufactured at NMT to make sure they were meeting the performance criteria with migration resistance? 03:42:04

A. Yes, we did.

Q. All right.

MR. NORTH: If we could bring up 5523, please. 03:42:18

BY MR. NORTH:

Q. Do you recognize 5523?

A. Yes.

Q. And what is this?

A. It is the report of the tests that you just mentioned. 03:42:32

MR. NORTH: Your Honor, at this time we would tender 5523.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 5523 was admitted into evidence.) 03:42:43

MR. NORTH: If we could display this to the jury.

THE COURT: You may.

MR. NORTH: And go to page five.

BY MR. NORTH:

Q. Did this test, again, test the migration resistance for 03:43:01

two different diameters of simulated inferior vena cavas? 03:43:04
A. Yes. For 15 and 28 millimeters.
Q. And then if we could go to page seven, please. And what was the conclusion?
A. That Recovery filters manufactured at Glens Falls operations, is what GFO stands for, meet the migration acceptance criteria and sample population mean is equivalent to the NMT sample population mean in the 28 millimeter diameter cava. Sample populations tested using the 15 millimeter diameter simulated IVC were not statistically compared since 03:43:29 03:43:48
the NMT and the Nitinol Medical and the Glens Falls fixtures had a different maximum pressure that could be obtained which distorted the data.
Q. After you conducted these various tests, how -- did Bard then begin selling this product to doctors? 03:44:15
A. Yes.
Q. And did Bard receive clearance from the FDA to begin selling the Recovery filter as a permanent device initially?
A. Yes.
MR. NORTH: If we could bring up 5189. I am not certain if this has been admitted yet. 03:44:29
COURTROOM DEPUTY: 5189 is admitted.
MR. NORTH: It is admitted?
MR. LOPEZ: Your Honor, may I just ask, is this subject to the agreement, though, to review it for purposes of 03:45:06

other hearsay? 03:45:09

COURTROOM DEPUTY: Yes, it is.

THE COURT: Yes, it is.

MR. LOPEZ: Thank you, Your Honor.

BY MR. NORTH: 03:45:14

Q. Is this the submission to the FDA regarding -- let's look at the second page if we could actually. Seeking the initial clearance of the device as a permanent filter?

A. Yes.

Q. And were you involved in the preparation of this 510(k)? 03:45:31

A. Yes.

MR. NORTH: If we could turn to page 18. If we could just display this page.

THE COURT: Any objection to this page, Mr. Lopez?

MR. LOPEZ: No, Your Honor. 03:45:56

THE COURT: You mail.

BY MR. NORTH:

Q. What does page 18 demonstrate here?

A. It is the summary of the design control activities that were done to support this submission. 03:46:08

Q. And does it provide you, provide an actual list of the tests that had been performed there on the right?

A. Yes.

Q. And had all of those tests been performed on the Recovery filter? 03:46:26

A. Yes. 03:46:27
Q. What is clot trapping efficiency testing?
A. It is how well a filter traps the clots that are coming from below. So the object of a filter is to prevent those clots. 03:46:52
Q. And we talked about migration studies; correct?
A. Yes.
Q. What about weld integrity, what is that testing for?
A. It tests the joints and the bonds of different parts of the system on the delivery system as well as the filter. 03:47:01
Q. And what about hook strength?
A. Measures the force required to straighten the hook. The hook is a half a circle, if you will, shaped and the way it comes out of the vena cava is to truly straighten out and so we measure that force. 03:47:23
Q. And we talked about the corrosion or fatigue testing; correct?
A. Yes.
Q. What about radial strength, what does that test?
A. Radial strength tests the outward force of the elements, so as they are constrained, they have an opposite force that's applied outward. 03:47:34
Q. And what is spline glue joint tensile test?
A. It is the test of the glue joint. It is a test where we measure a bond of a piece we call the spline that is glued onto 03:48:03

a wire and that piece can't move so we pull it to measure that force. 03:48:09

Q. And a simulated use study?

A. Is the animal studies.

Q. Now, did Bard provide the FDA with actual information concerning those studies? 03:48:27

A. Yes.

Q. Did they provide test reports or summaries or what was the form of the information provided?

A. Might have been summaries at first and ultimately the reports. 03:48:41

MR. NORTH: If we could look at 5187, please.

BY MR. NORTH:

Q. Once the 510(k) was submitted in the summer of 2002 to the FDA for clearance of the device Recovery filter as a permanent filter, did the FDA pose a number of questions to the company? 03:49:22

A. Yes, they did.

Q. And did they -- did the company receive those questions from the agency?

A. Yes. 03:49:42

Q. And were the questions shared to you -- with you once they arrived.

A. Yes.

Q. And did a number of those questions deal with the testing of the filter? 03:49:53

A. Yes. 03:49:54
Q. And do you recognize the letter dated August 5 of 2002 that is Exhibit 5187?
A. Yes.
Q. And did the company receive this as a part of its routine 03:50:03 business practices?
A. Yes.
Q. And did you maintain this letter in your business files?
A. Yes.
MR. NORTH: Your Honor, at this time we would tender 03:50:15 5187.
MR. LOPEZ: No objection, Your Honor.
THE COURT: Admitted.
(Exhibit Number 5187 was admitted into evidence.)
BY MR. NORTH: 03:50:26
Q. And what involvement did you have personally in preparing the response to this letter?
A. I was very much involved in both answering questions, reviewing the answers that I didn't write.
Q. Do you recall how many different questions the agency 03:50:50 asked Bard regarding the Recovery filter submission?
A. I think 17.
Q. Let's start and look at page two if we could.
MR. NORTH: Could we display this to the jury, Your Honor? 03:51:03

THE COURT: You may. 03:51:03

BY MR. NORTH:

Q. Did the agency ask some questions about the bench performance testing Bard had conducted?

A. Yes. 03:51:16

Q. What sorts of things were they inquiring about?

A. The first one or question three is about the clot-trapping efficiency and the center one is about clot-trapping efficiency again.

Q. Let's go down to number eight. What were they asking about there? 03:51:41

A. It's about caval perforation, does the filter go through the caval wall?

Q. What about in question number nine, what was the agency asking about? 03:51:58

A. Corrosion and fracture resistance.

Q. Did they request additional data?

A. They did.

Q. Concerning what?

A. The integrity of the device. 03:52:10

Q. Let's go to the next page and look at question 12. What were they inquiring about there?

A. The weld integrity of the device which is at the tip of the filter.

Q. Let's look at question 14. What were they inquiring about 03:52:39

there? 03:52:41
A. The radial strength.
Q. And what about in question 15 and 16?
A. Those refer to biocompatibility testing.
Q. And what is that test for, biocompatibility? 03:52:52
A. To show that the device doesn't have a reaction in the body essentially.
Q. In question 15, did the agency specifically refer you to the IVC filter guidance we had discussed?
A. Yes. 03:53:09
Q. Did Bard respond to these questions?
A. Yes, we did.
MR. NORTH: Let's pull up Exhibit 5182 if we could.
Q. Do you recognize 5182?
A. Yes. 03:53:35
Q. And what is that?
A. It is our response to their questions.
Q. And who actually prepared this response?
A. Many people helped prepare it.
Q. And is this maintained in Bard's business records? 03:54:06
A. Yes.
MR. NORTH: Your Honor, at this time we would tender 5182.
MR. LOPEZ: Subject to our agreement to discuss, hearsay within hearsay. 03:54:14

THE COURT: All right. Admitted subject to that agreement. 03:54:15

(Exhibit Number 5182 was admitted into evidence.)

BY MR. NORTH:

Q. If we could display page 11. I don't believe this will implicate the agreement. 03:54:29

MR. LOPEZ: No objection, Your Honor.

THE COURT: You may display it.

BY MR. NORTH:

Q. Is this where the company is providing information to the agency in response to questions concerning fatigue and corrosion testing? 03:54:53

A. Yes, question nine.

Q. If we could go to the next page.

Did you talk here and provide the agency with any details about the cycles that had been done with the some of the fatigue testing? 03:55:25

A. Yes. All filters at the bottom there met the acceptance criteria after ten years, pulmonary output greater than 32 million cycles. 03:55:46

Q. As we discussed earlier, did the company go beyond 32 million cycles?

A. Yes. We carried it out to about 417 million.

Q. Did the company provide the agency with actual test reports and test protocols that were attached to this letter? 03:56:03

A. Yes.
Q. Did they provide the agency with actual test results for simulated use testing?
A. Yes, we would have provided everything they asked for.
Q. So after Bard sent this letter in the end of August of 2002, did the FDA come back with additional questions to Bard concerning the Recovery filter?
A. Yes.
MR. NORTH: If we could look at Exhibit 5179.
BY MR. NORTH:
Q. Do you recognize Exhibit 5179?
A. Yes.
Q. And is it a letter received October 4 of 2002?
MR. LOPEZ: No objection to foundation, Your Honor, or admission subject to our hearsay discussion.
MR. NORTH: I will tender the exhibit, Your Honor.
THE COURT: All right. Admitted subject to the parties' review.
(Exhibit Number 5179 was admitted into evidence.)
THE WITNESS: I'm sorry. What was the question?
BY MR. NORTH:
Q. Was the letter received on October 4, 2002?
A. Yes.
Q. A little over a month after Bard had sent its responses to the FDA?

A. Yes. 03:57:24
Q. And did the FDA ask some additional questions as a part of this letter?
A. Yes, they did.
Q. Let's look at question one if we can. 03:57:37
MR. NORTH: If we could display this, Your Honor.
THE COURT: You may.
BY MR. NORTH:
Q. Did the agency ask you questions then about -- further questions about the clot-trapping deficiency testing? 03:57:54
A. Yes, they did about the size of the clots used.
Q. And if we could go down to number two. Did they ask you questions about radial strength testing?
A. Yes, they did.
MR. NORTH: Now if we could go to Exhibit 5178. 03:58:20
BY MR. NORTH:
Q. Did Bard respond approximately three weeks later to the agency's second set of questions regarding the Recovery filter?
A. Yes.
Q. And is this letter the response that was sent to the FDA concerning its questions? 03:58:48
A. Yes.
Q. And, again, were you involved in fashioning this response?
A. Yes.
MR. NORTH: Your Honor, we would tender 5178. 03:59:03

MR. LOPEZ: No objection, Your Honor. 03:59:06

MR. NORTH: If we could display this, please.

THE COURT: Yes.

(Exhibit Number 5178 was admitted into evidence.)

MR. LOPEZ: May I see the signature page before we move on? 03:59:14

THE COURT: Yes.

MR. LOPEZ: And, again, this is still subject to our agreement on these type of documents?

THE COURT: All right. Admitted subject to that agreement. 03:59:21

MR. NORTH: Could we display page two, please.

BY MR. NORTH:

Q. So did the company provide the FDA with additional information in response to its various inquiries? 03:59:41

A. Yes, we did.

Q. After the company submitted this additional information, did the FDA then clear the Recovery filter for permanent use?

A. We received concurrence, yes.

Q. Now, thereafter, the next year, the company then sought clearance of the Recovery filter for use as a retrievable device; correct? 04:00:18

A. Yes.

Q. And did the agency again ask a series of questions of the company when you sought clearance for retrievability? 04:00:29

A. Yes.

MR. NORTH: If we could look at Exhibit 6082.

BY MR. NORTH:

Q. Did the agency sometimes communicate with Bard in posing questions by email as opposed to formal letter?

A. Yes.

Q. And do you recall getting email requests from the FDA regarding this particular 510(k) submission or do you recall the company getting emails?

A. Yes.

Q. And would you have been involved in responding to those emails?

A. Yes.

Q. And would those emails then have been kept as a part of the formal correspondence file and business records of the company for the 510(k)?

A. Yes.

MR. NORTH: Your Honor, at this time we would submit 6082.

MR. LOPEZ: I think we have a 602 issue as well as an 802. I don't think he's on the emails.

THE COURT: To establish this as a business record, Mr. North, I think he has to have knowledge with respect to this specific document and I don't think you've established that.

BY MR. NORTH: 04:01:57
Q. Mr. Carr, did you see this particular document when it arrived at the company, these emails?
A. I'm sure that we reviewed it.
Q. Did you assist the company in responding to the emails? 04:02:07
A. Yes.
Q. And do you specifically recall having worked on those responses?
A. Yes.
MR. NORTH: Your Honor, at this time we would tender 04:02:18
it.
MR. LOPEZ: I'm still not sure he satisfied 602, Your Honor.
THE COURT: I'm going to overrule 602. And you made an 802 objection? 04:02:29
MR. LOPEZ: Yes, I did. I'll add that.
THE COURT: Okay. What's the defect on the business records in your view?
MR. NORTH: I'm sorry, Your Honor?
THE COURT: I'm asking this to Mr. Lopez. What's the 04:02:39
defect on the business records foundation?
MR. LOPEZ: Well, I'm not sure it's a business record. It's an email communication between two people whose names I don't recognize. If we can establish who these people are, maybe it would help a little bit. 04:02:57

BY MR. NORTH: 04:03:04

Q. Do you know who Lisa Kennell is?

A. Yes. She was an FDA reviewer.

Q. Was she the FDA person in charge of reviewing the Recovery filter applications or submissions, to your knowledge? 04:03:12

A. I don't know if she was in charge but she was the reviewer.

Q. And do you know who Aymee Berry is or was?

A. I think she still is. She was a regulatory person at Bard. 04:03:28

MR. LOPEZ: Your Honor, I just noticed this is not even a Bard document.

THE COURT: Well, rather than keep the jury waiting, why don't we continue this discussion after we're finished and that way I can hear you out fully without keeping them waiting. 04:03:43 If you can move on with other questions, Mr. North.

MR. NORTH: Sure.

If we could bring up 5164, please.

BY MR. NORTH:

Q. Do you recall seeing 5164, Mr. Carr? 04:04:07

A. Yes.

Q. And what is this document?

A. It's a fax at the time back to the FDA for the stability protocol, the test report, the adoption rationale and the accelerated aging protocol for the filter. 04:04:28

Q. Were you involved in any way in preparing -- 04:04:34

MR. NORTH: Let's go to the next page if we could. The next page after that.

Q. -- in preparing this information, collecting this information? 04:04:49

A. Yes.

Q. And was this in response to the FDA's latest round of questions that we were just reviewing?

A. Yes.

Q. And is this response maintained in the business records of the company? 04:04:57

A. Yes.

Q. Ed?

MR. NORTH: Your Honor, at this time I would tender 5164. 04:05:05

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 5164 was admitted into evidence.)

MR. NORTH: If we could go back to the first page and, Your Honor, publish that to the jury. 04:05:17

THE COURT: You may.

BY MR. NORTH:

Q. What test reports were you furnishing the FDA at the agency's request in response to these questions?

A. A Stability Protocol and the associated report, a what we 04:05:36

call a SPAR, a Stability Product Adoption Rationale, and an Accelerated Aging Protocol. 04:05:43

Q. What are the stability reports and tests, what do those concern?

A. We have what's called a shelf life of the product, so how long from the date it's manufactured to the time it can be used by the physician. 04:05:57

Q. After you finished this additional information to the agency, did the FDA clear the Recovery filter for retrievable use? 04:06:15

A. As an optional filter, yes.

Q. Mr. Carr, when did you start the development process for the G2 filter?

A. I think in 2004.

Q. And why did Bard decide to start developing the G2 filter? 04:06:38

A. We always want to replace yourselves and as we see opportunities to make next generation or advancements to our products, we do that so others don't.

Q. And what were the specific design attributes that Bard was seeking to improve upon? 04:07:01

A. Migration resistance, also fatigue resistance and centering.

Q. During the time the Recovery filter was on the market, were you involved in the investigation of reports of patient death? 04:07:22

A. Yes. 04:07:25
Q. And we've heard testimony in this trial about the first report coming in in February of 2004 about a patient death in Miami. Did you get involved in the investigation of that event? 04:07:39
A. Very.
Q. Tell me what role you played personally in that investigation, Mr. Carr.
A. About a day or two after it happened, I personally flew to Miami and met with the physician who implanted the device, 04:07:52
their Risk Management group at the hospital, and we began an investigation to figure out everything we could about what happened in that case.
Q. And what did you learn as part of your investigation of that event? 04:08:17
A. The filter was overcome by massive clot.
MR. LOPEZ: Your Honor, I think this is asking for a narrative that may include a lot of hearsay, so I'm going to object on those grounds.
THE COURT: Well, there has been no hearsay 04:08:28
requested. He just asked a question so I'm going to overrule that objection.
THE WITNESS: So we were at the hospital and saw the actual clot that had overcome the filter; and as I said, it was massive and the physician who we were working with was also 04:08:47

very surprised at the size that it was. And so the filter was nearly completely encased in the clot and, unfortunately, it was in the patient's heart. 04:08:55

After that we did a complete evaluation of the device itself, the manufacturing, was it made to specification, all of those kinds of things. 04:09:13

Q. Has the company received a few additional reports of patients who died with the Recovery filter in place? Did you notice any trend in attributes of those patients?

A. Yes. They were -- most had been overcome by a large clot and several were bariatric patients or patients having gastric bypass surgery. 04:09:47

Q. What sort of investigative activities did the company and you yourself conduct in those -- during that time period as these reports came in? 04:10:10

A. We were speaking with our consultants on a very routine basis, that would be Dr. Kaufman and Venbrux. We convened a panel of physicians to talk to them about what we were observing and was there anything in particular to learn about those patients that we didn't know before and we tried to learn everything that we could. 04:10:33

Q. So what specific changes just in general were made to see the Recovery filter to become the G2?

A. So we made the base of the filter wider so -- arms and legs is how I refer to the two levels of the filter. And where 04:11:04

the arms came out of the tube at the top, we changed that angle and made it -- we removed the stress from that paint. 04:11:09

As I said, we made the base of the filter wider. We made the arms longer and we also increased the diameter of the wire that makes the hook. 04:11:30

Q. Now, if we could display, show 5296. What is a PPS, Mr. Carr?

A. It is a Product Performance Specification.

Q. And what does that mean?

A. It defines the different specifications or attributes that any device -- in this case a filter -- must meet. 04:11:57

Q. And what is the purpose of the PPS?

A. To identify potential causes of complications and then to mitigate those through design and testing.

Q. This PPS appears to be for the modified Recovery filter. What is that? 04:12:32

A. It's what became the G2.

MR. NORTH: Your Honor, at this time I would tender 5296.

MR. LOPEZ: Can I just see the rest of the document, Your Honor. 04:12:44

MR. NORTH: Can you scroll to the next page?

MR. LOPEZ: Just two pages?

MR. NORTH: It's 30 papers.

MR. LOPEZ: Oh, I don't need to see them all. 04:13:02

There's no objection, Your Honor. I've seen this document before. 04:13:04

THE COURT: All right. 5296 is admitted.

(Exhibit Number 5296 was admitted into evidence.)

MR. NORTH: Could we display, Your Honor? 04:13:11

THE COURT: You may.

MR. NORTH: Could we turn to page 17, please.

BY MR. NORTH:

Q. Does this document reference the tests that had been performed in the development of the G2? 04:13:27

A. Yes. The right most column where it says reference documents, those are the actual documents that support that row or design characteristic.

Q. And this reflects tests concerning what attributes of the G2 filter? 04:13:53

A. On this page, filter migration, radial strength, weld strength, and hook creep resistance.

Q. And did the device pass or fail those tests?

A. Ultimately, it passed them all.

MR. NORTH: Let's look at the next page if we could. 04:14:14

BY MR. NORTH:

Q. Does this reflect additional tests that were performed?

A. Yes.

Q. What are those tests?

A. Fatigue resistance, two different ways to test it, filter 04:14:26

centering, the removal force of the filter and also kink resistance of the delivery system. 04:14:31

Q. And did the device, the G2, pass or fail those tests?

A. It passed.

MR. NORTH: If we could go to the next page. 04:14:51

BY MR. NORTH:

Q. Does this reflect additional tests that had been conducted?

A. Yes.

Q. Do most of these tests concern -- what do they concern? 04:14:57

A. The delivery system.

Q. And did the device pass or fail the test?

A. It passed.

MR. NORTH: Next page, please.

BY MR. NORTH: 04:15:12

Q. Are these additional tests that the filter passed?

A. The delivery system in particular, yes.

MR. NORTH: And the next page, please.

Q. Is this, again, in the delivery system?

A. Yes. 04:15:31

Q. And did the filter pass all of these tests?

A. Yes.

Q. Was animal testing performed on the G2?

A. Yes.

Q. And were there two types of animal testing again? 04:15:46

A. Yes. The same battery of tests. 04:15:49

MR. NORTH: If we could pull up 5301.

BY MR. NORTH:

Q. Do you recognize this document, Mr. Carr?

A. Yes. 04:16:10

Q. And what is this?

A. It's the animal report for G2.

Q. Now, it says for the Recovery filter G1A. Is that what eventually became the G2?

A. It is. 04:16:24

MR. NORTH: Your Honor, at this time we would tender 5301.

MR. LOPEZ: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit Number 5301 was admitted into evidence.) 04:16:32

BY MR. NORTH:

Q. And, again, what sorts of attributes were these animal tests?

A. There was the acute testing which, again, tested deployment accuracy and centering and the ability to -- for the delivery system to get to the intended site and then the chronic testing which tested the removability of the device longer term. 04:16:47

MR. NORTH: And if we could put up 5304, please.

Q. Is this another test, the chronic animal test, performed 04:17:12

on the G2? 04:17:16

A. Yes, it's the report from chronic the test.

MR. NORTH: Your Honor, at this time we would tender 5304.

MR. LOPEZ: No objection. 04:17:24

THE COURT: Admitted.

(Exhibit Number 5304 was admitted into evidence.)

BY MR. NORTH:

Q. Did the filter, the G2, pass all of these animal tests?

A. Yes. 04:17:33

MR. NORTH: Now if we could, let's look at 5302.

MR. LOPEZ: No objection, Your Honor.

MR. NORTH: It may have been admitted. I'm not sure.

COURTROOM DEPUTY: 5302 is not admitted.

MR. NORTH: Okay. Yes. 04:17:56

THE COURT: Are you moving it into evidence?

MR. NORTH: Yes, Your Honor. I'm sorry.

THE COURT: All right. It's admitted.

(Exhibit Number 5302 was admitted into evidence.)

MR. NORTH: Could we display this to the jury? 04:18:08

BY MR. NORTH:

Q. Tell the members of the jury what this particular report concerns.

A. This is the protocol for the testing for the design verification and validation of the G2 filter. 04:18:30

Q. How does design verification and validation fit into the product development cycle we discussed earlier? 04:18:33

A. It's the ultimate testing prior to submission, it's the battery of tests that are used to satisfy the guidance documents and incorporate it in the regulatory submission. 04:18:53

MR. NORTH: And then if we could show 5303 which I do think has been admitted.

THE COURT: It's in evidence.

MR. NORTH: And if we could display that to the jury, please. 04:19:15

THE COURT: Yes.

BY MR. NORTH:

Q. I believe you said the last document we looked at was the protocol. Is this the actual test document itself?

A. Yes. This is the report. 04:19:26

MR. NORTH: If we could look at page nine, please.

BY MR. NORTH:

Q. Does this begin a lengthy discussion of the test results and summary of the data regarding the development of the G2 filter? 04:19:49

A. Yes. We go through each and every test.

Q. If we go to the next page, 10, does this show more tests?

A. Yes.

Q. Page 11, please. And more?

Page 12. Are these additional tests? 04:20:08

A. Yes. 04:20:13
Q. Page 13?
A. Yes.
Q. Did the G2 filter pass all of these tests?
A. Ultimately, yes. 04:20:26

THE COURT: We are at 4:20 Mr. North so we are going to break for the day. Ladies and gentlemen, we'll plan to see you at nine tomorrow morning. Thanks for your attention today.

We will excuse the jury.

(Jury departs at 4:20.) 04:20:42

THE COURT: Go ahead and step down. Let me give you your time, counsel, and then I just want to talk about a couple of other matters.

All right. Counsel, as of the end of today, plaintiff has used 27 hours and two minutes; defendants have 04:22:43 used 16 hours and seven minutes. We entered an order this morning that ruled on the three deposition designations that the defendants asked that I rule on over the weekend.

I have not had time yet to read the FDA letter briefs. I'll look at those this evening. We need to talk 04:23:10 about Exhibit 6082 which is the one that we were discussing while the jury was waiting.

MR. NORTH: Your Honor, I'm sorry. I can short-circuit that. I'll withdraw it because I think the response handled everything I need. 04:23:31

THE COURT: Okay. And then, lastly, we have jury instructions to give you. I'm going to give you a set that is red-lined so that you can see what I changed from the last version and a clean set so that you can review those, too. 04:23:33

When you look through them, you'll note that a number of them are things that we more or less agreed on when we talked last. I am still considering what we ought to do on the intervening cause instruction. We did make one overall change and that is we reworded it to match the wording in the restatement which we thought was just clearer. The restatement talks about a superseding cause which comes about by an intervening act rather than an intervening cause, and I thought that was more consistent with the notion of intervening cause. It has to, in effect, supersede any proximate cause that was attributable to the defendant. But look at that language and see what you think. 04:23:56 04:24:20 04:24:39

We found nothing in the restatement on this question of whether intervening cause can be for part or all. We found one case, one old case, where the instruction was given that it can be for part. It's not a Georgia case. There seems to be a date of birth of authority on this issue. 04:24:55

I've reread *Coleman* today. I want to think about it a bit. So my point on that is, I'm still interested in your comments tomorrow evening on the intervening cause instruction. We changed Bard to singular throughout the instructions, made a 04:25:15

number of other changes that we had talked through with you. We modified the verdict form to match that and include the burdens of proof on each of the issues that the jury is asked to rule on. 04:25:20

So please given those a careful review because tomorrow evening will be really the full opportunity I'll have to hear any other comments you have. I'm not going to have time Wednesday evening; and, in fact, we may, depending on how long the cases take, present the instructions to the jury before the close of the day on Wednesday. 04:25:31 04:25:47

If you have proposed instructions you want me to consider tomorrow, you need to hand them to me in writing rather than just talk about concepts. If you just talk about concepts, we're going to have to do some drafting and find another time to meet and confer and I don't think we'll have that opportunity on Wednesday. So I know one of the issues from both sides will be what to do with FDA instructions. If you think something different from what you submitted on that issue should be given, please have a draft of that ready for me to look at and any other instructions you want me to consider please have those ready for me to review. 04:26:07 04:26:20

Any questions on jury instructions?

Have I left anything out, Jeff? Anything?

Okay.

MR. LOPEZ: Your Honor, I know you have a hearing but 04:26:42

we need to address this time issue. I have too much to say about that right now. 04:26:43

THE COURT: What do you mean the time issue?

MR. LOPEZ: The amount of time that we have left to finish this mini-trial on the FDA which is of concern to us. We're not going to have an opportunity to finish cross-examining these people and have time to argue the case, it's clear. 04:26:50

THE COURT: Well, I've given you two additional hours. 04:27:04

MR. LOPEZ: Well, you know, I mean, again, when we agreed for this to be a 12-day trial, we didn't anticipate -- we both -- look it, both sides I think read the tea leaves wrong. We had a case in Florida where both sides -- defense didn't want to stipulate to your ruling, what your ruling was going to be on that issue. 04:27:21

So, I mean, we're living this mini-trial right now that the Fourth Circuit and the 11th Circuit talk about and keeping this kind of evidence out. If this was just a case about 510(k) clearance process, we would be fine with that. We're having to deal with every single communication back and forth between FDA, whether or not FDA issued a recall. We've got to figure out a way to deal with that, ask lots of questions about that. 04:27:36

All I'm telling you, Your Honor, is we've gotten rid 04:27:58

of three experts to try to squeeze this case into the time allotment and we've taken down six or seven depositions we would have loved to have played and which means that we're not getting in a lot of the documents that we were hoping to get in. 04:28:00 04:28:13

You know, we feel okay about our case, don't get me wrong, but there's no way that we're going to be able to appropriately cross-examine the folks that are left, including Mr. Carr, in 30 minutes and leaving us an hour and a half to argue the case and maybe do a little bit of rebuttal and have a few minutes left to argue punitive damages. It's just not going to happen. We're going to be faced with a situation where if this time is imposed upon us as strictly as it currently is, we're just going to have to sit here for the last two or three witnesses and not cross-examine them and not argue our case. 04:28:33 04:28:51

THE COURT: Mr. Lopez, my view of this trial is that you have wasted six or seven hours in repetitious work in the trial. On Friday afternoon I watched two hours of deposition testimony that you presented. I watched the clock to see how much of that was new and, by my view, 15 minutes of that two hours was evidence that had not already been presented multiple times. 04:29:11

On one of the witnesses today, the defense attorney asked the exact same question six times, and I counted them. 04:29:26

There's been that kind of repetitious from the beginning so I cannot accept the proposition that you have been short-changed on time. You've chosen to emphasize the things you have I think for good strategic reason. But you knew coming in you had 27 hours. I've increased that to 29. We don't have the ability to invent time and come up with it. And so if we're going to get this case to the jury on the time I told them we would get it to them, there is no additional time. 04:29:32 04:29:45

MR. LOPEZ: Well, Your Honor, they didn't ask for more time and we did. 04:30:04

THE COURT: And I gave it to you.

MR. LOPEZ: You gave half to them.

THE COURT: You think I should have just given it to you?

MR. LOPEZ: Well, we have the burden of proof in this case, Your Honor. I have done time cases before where we got a significantly more amount of time. 04:30:11

THE COURT: You have never mentioned that until now. In all of our discussions of time, you've never once suggested that plaintiff should have more time than defendants and this is the first time you've raised that. 04:30:24

MR. LOPEZ: Well, but here's the point. We're now seeing today, Friday, this FDA, FDA, FDA. We have to deal with that. We weren't -- I mean, again, this is the mini-trial that the Fourth Circuit and 11th Circuit talk about. We had no idea 04:30:46

that the kind of evidence -- we can deal with it but not in the next two hours or the next hour. 04:30:50

THE COURT: The problem I have with that, Mr. Lopez, is that you waited to bring the Cisson motion, which had a massive effect if I would have granted it, on the nature of this case until we got to motions *in limine*. You never raised it earlier as something that could focus the discovery when we were talking about trial times. 04:31:04

I can't accept the proposition that the plaintiffs' group prepared this case on the assumption that the FDA evidence wouldn't be in the trial. 04:31:23

MR. LOPEZ: Well, we did. We did. I mean, the consistent rulings --

THE COURT: And why did you designated FDA experts?

MR. LOPEZ: Well, I mean, the ruling hadn't come out. 04:31:36

THE COURT: You hadn't asked for it earlier either.

MR. LOPEZ: You don't need an FDA expert just on -- we're not calling an FDA expert.

THE COURT: I know but you designated one suggesting you knew the FDA issues were in the case. 04:31:47

MR. LOPEZ: Well, because they were. They were at the time that we designated them.

THE COURT: And they were at the time we set the hours. They were at the time you told me this was a three-week trial. 04:32:01

You can I can debate this all day. 04:32:02

MR. LOPEZ: We could.

THE COURT: And there's no point. My concern is we have stretched this case to the point where if we're going to get -- if there's a ruling in favor of punitive damages and 04:32:12 we're going to get that issue to the jury and give them time to deliberate, I don't think there's a way to find more time in this case.

MR. LOPEZ: Well, Your Honor, let me put it this way. Originally we got 12 days to try this case and this is day 04:32:24 nine. Is it day nine? No. Three plus four -- this is day eight. We were given 12 days to try this case.

THE COURT: Which included jury selection and which included jury deliberation.

MR. LOPEZ: I counted that. I counted the three 04:32:45 days, Wednesday, Thursday, Friday, last week four, and today. That is eight days.

And, you know, we asked for 12 and, in fact, when you took one away, we had a phone call. I called you because I was concerned about that. And I said, no, Your Honor, we need that 04:33:01 day back.

THE COURT: And I have gave it to you back this last Monday.

MR. LOPEZ: Well, okay. I understand we've added minutes and we've added hours to it but we're at day eight and 04:33:13

we agreed to a 12-day trial and I didn't know -- there was never any discussion about that including deliberations until about two or three weeks ago. That was 12 days I thought to try this case because we can't tell how long this jury is going to deliberate. They could deliberate for a week. 04:33:19 04:33:34

When we agreed to a 12-day trial, we thought we were going to have 12 trial days including argument and including instruction and including opening, all of that. But to be part of the case before it went to the jury. Right now we're going to get ten because you're talking about maybe instructing Wednesday. 04:33:50

THE COURT: When we sent out the jury questionnaire that said this trial would end on Friday, I heard no objection from you that your anticipation was that we would finish closings on Friday and the jury would start deliberating on Monday and we told the jury in the questionnaire the trial would last through Friday. 04:34:05

Again, we could debate this all day and I don't want to do that.

MR. LOPEZ: Well, Your Honor, I'm doing this because I think it's in the best interest of Ms. Booker and I have to advocate for her. 04:34:19

THE COURT: I understand that but as I've indicated, I think there's been lots of time that could have been saved along the way in the plaintiff's case. 04:34:30

MR. LOPEZ: Well, the last thing I want to do is argue with the judge sitting on my case. 04:34:34

THE COURT: You can argue with me. I'm not taking offense at it. I'm just telling you why I don't think you have been treated unfairly on the matter of timing. 04:34:44

MR. LOPEZ: Well, the depositions that we've played, there were a lot of them, different pieces of evidence came in in each one of those depositions. They were played specifically to get into evidence certain documents. We didn't even -- we cut out the discussion on some of those documents to the extent that we would have liked to have played that. 04:34:56

Maybe we haven't been as efficient as we could have been but I don't think that we've wasted a lot of time. I mean, we're advocates. We're trying to advocate. Sometimes the witnesses, you know, they are not quite as cooperative with us as they are with counsel on the defense side. Sometimes we've got to go at them two or three times before we get an answer. We have to stop and read a deposition. 04:35:17

THE COURT: Let's talk about the schedule for a minute. If we use all of the time that has been allotted, we will get the case to the jury at about -- without the punitive damages issue having been addressed, including the potential deliberation on that, by mid-afternoon on Thursday and then if they agree to punitive damages, we'll need to do argument and evidence on that as well. 04:35:31 04:35:53

Where are you suggesting we find the additional time? 04:35:55

MR. LOPEZ: Well, why can't we argue the case, you know, Thursday afternoon?

THE COURT: You're going to and they will walk out of the courtroom at 2:30 according to my calculation of the time 04:36:07 that has been allowed.

MR. LOPEZ: All I'm saying is, when we agreed to 12-day trial, we thought it was going to include putting on evidence. And, again, I agree it was going to include jury selection, opening and closing. But never did I take -- did I 04:36:22 think that was going to include deliberation because who knows how long that's going to be?

THE COURT: Well, I understand what you've said. I want to stick with the schedule that we've got. If you want to raise it again as we go along, you are welcome to do that but I 04:36:42 have been giving you time every day so you have been able to allocate it. And I think there has been ample time for you to get in your evidence and have time to cross-examine defense witnesses and argue.

MR. LOPEZ: Well, Your Honor, if they don't use all 04:36:56 their time, just so we can have -- we can have a fair opportunity to cross-examine during the defense case.

THE COURT: We'll have to cross that bridge when we get there because at this point, I don't know.

Do you know, Mr. North, if you're going to use all 04:37:10

your time? 04:37:12

MR. NORTH: I think we will, Your Honor. I mean, we are going to reserve some time, which I think we should be entitled to, for closing argument, of course, and we have to save time for rebuttal, closing, and the punitive phase, but, 04:37:21 yes.

MR. LOPEZ: So two hours from now we're going to get shut down? I just need to know.

THE COURT: Well, you have an hour and 58 minutes that you've allotted. 04:37:37

We can talk about it at the end of tomorrow and see where you are, but I'm not going to push this argument into Friday and without us having even gotten to punitive damages. As I indicated, I think there has been ample time to try the case. 04:37:57

MR. LOPEZ: Okay.

THE COURT: All right. Are there other matters that we need to address before we break?

MR. LOPEZ: No, Your Honor. Thank you.

MR. NORTH: Nothing, Your Honor, other than if the 04:38:04 Court ever were to be so inclined to change the time allocations, I would want to be heard at that point.

THE COURT: I assume you would. I understand that. Okay. Thank you.

(Whereupon, these proceedings recessed at 4:38 p.m.) 04:38:13

C E R T I F I C A T E

I, ELAINE M. CROPPER, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 26th day of March, 2018.

s/Elaine M. Cropper

Elaine M. Cropper, RDR, CRR, CCP